MEDICARE DRUG REIMBURSEMENTS: A BROKEN SYSTEM FOR PATIENTS AND TAXPAYERS

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

AND THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

SEPTEMBER 21, 2001

Serial No. 107–65

Printed for the use of the Committee on Energy and Commerce

Available via the World Wide Web: http://www.access.gpo.gov/congress/house

U.S. GOVERNMENT PRINTING OFFICE

75–756CC WASHINGTON : 2001

For sale by the Superintendent of Documents, U.S. Government Printing Office
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MEDICARE DRUG REIMBURSEMENTS: A BROKEN SYSTEM FOR PATIENTS AND TAXPAYERS

FRIDAY, SEPTEMBER 21, 2001

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEES ON HEALTH,
AND OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittees met, pursuant to notice, at 9:40 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis and Hon. James C. Greenwood presiding.

Members present Subcommittee on Health: Representatives Bilirakis, Barton, Upton, Greenwood, Burr, Ganske, Norwood, Bryant, Buyer, Pitts, Tauzin (ex officio), Brown, Barrett, Capps, Hall, Pallone, Deutsch, Stupak, Engel, and Green.

Members present Subcommittee on Oversight and Investigations: Greenwood, Bilirakis, Stearns, Gillmor, Largent, Burr, Bass, Tauzin (ex officio), Deutsch, and Stupak.

Staff present: Chuck Clapton, majority counsel; Yong Choe, legislative clerk; and Edith Holleman, minority counsel.

Mr. GREENWOOD. Good morning. This joint hearing of the Energy and Commerce Committee's Subcommittees on Oversight and Investigation and Health will now come to order. Before we proceed with the members' opening statements, Mr. Bilirakis and I would like to make a few remarks.

Among the thousands of lives so hideously taken from us on September 11 was that of Lisa Raines. Lisa Raines was the senior vice president of government relations for Genzyme Corporation. Those of you who knew her know she was a giant in the biotech and pharmaceutical industry for at least the past 15 years and a friend to many. Her memorial service is scheduled for 11 o'clock this morning, and for that reason these subcommittees considered very seriously postponing once again this hearing. We wish we could have done that.

By the conclusion of this hearing, I think it will be apparent to all the urgency to fix this broken AWP system. Given the fact that we have only about 4 weeks for session for this year, we concluded that it was impossible, particularly given next week's short schedule, to postpone this hearing once again. We regret we had to make that decision because we know there were many who would like to be here, but also felt their priority was to be at the memorial service.

Having said that, I would like to recognize Chairman Bilirakis for his comments.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

On September 11 of this year, American's calm was shattered by a horrendous act of terrorism that will long be remembered. Our thoughts and prayers are with those whose lives have been forever altered by this tragedy.

When American Airlines flight 77 went down, the health community lost a dear friend and respected colleague, Lisa Raines. Lisa was a senior vice president of government relations for Genzyme Corporation. Lisa had worked closely and often with the Energy and Commerce Committee through the years, working to enact the Drug Export Amendments Act of 1986, the prescription drug user fee, PDUFA, the FDA Export Reform and Enhancements Act of 1996, and the Food and Drug Administration Monitorization Act, or FDAMA.

A vital member of the Washington biotechnology and pharmaceutical community, Lisa previously worked for the Industrial Biotechnology Association, now BIO, and the Congressional Office of Technology Assessment. Lisa's expertise and insight as well as her bright personality and charm will be missed by this committee, the Congress and the health community. I think the publication BioCentury said it best when it said Lisa was as much a fixture of the biotech industry as a double helix, and it is hard to comprehend that she is gone. She leaves a hole in the industry's relationship with the outside world that will be difficult to fill.

I join with the chairman and members of this committee as we offer our condolences and prayers to Lisa's family and friends. Please join us in a moment of silence in honor of Lisa Raines.

[The prepared statement of Hon. Michael Bilirakis follows:]

PREPARED STATEMENT OF HON. MICHAEL BILIRAKIS, CHAIRMAN, SUBCOMMITTEE ON HEALTH

I'd like to thank Chairman Greenwood for joining me today to examine the issues surrounding the current system for Medicare drug reimbursement. The Health Subcommittee has spent a considerable amount of time in this Congress examining how best to add a comprehensive prescription drug benefit to the Medicare program. This hearing builds off of work we began in the last Congress where we examined the reimbursements for the limited drug coverage currently available in the Medicare program.

I'd like to welcome and thank all of the witnesses, including Tom Scully from CMS and Bill Scanlon from GAO. We rely often on these government officials and their offices for factual information and detailed analysis, thank you for coming today. I'd also like to welcome Mr. Zachary Bentley from my home state of Florida. I know that your testimony, and that of all the witnesses, will help inform the Committee and the public about the issues regarding Medicare's current reimbursements to health care providers for certain drugs used to treat patients.

The Medicare program currently provides coverage for a small number of drugs, limited principally to those that are administered incident to a physician's treatment or in conjunction with covered durable medical equipment, such as inhalation drugs used with a nebulizer. Since at least 1992, Medicare has determined the appropriate reimbursement price for these covered drugs by referring to an industry trade publication known as the Red Book, which lists what manufacturers purport to be the Average Wholesale Price for their drugs. Since 1997, providers who administer these drugs to Medicare beneficiaries have been reimbursed for their cost at prices equal to Average Wholesale Price (AWP) minus five percent. Of this set amount, Medicare Part B covers 80 percent, while Medicare beneficiaries can be required to pay the remaining 20 percent as a co-payment. Today's hearing will examine how Medicare's current reimbursement system, for the relatively few drugs that

are covered, is costing beneficiaries and taxpayers more than is necessary and may be having an adverse impact on the health of some of our most vulnerable citizens.

I recently toured a Clearwater oncology center in my Florida district and I can tell you what great work oncologists do and how important their work is to so many Americans. At the request of my constituent Dr. Marcos Joppert I would like to admit this white paper on oncology payments into the record.

This will prove to be a lengthy hearing and thus I will limit my opening statement so that we may get to the important testimony of the witnesses—who I again thank for their effort and cooperation.

Mr. GREENWOOD. Thank you, Chairman Bilirakis, for your comments. As the President said, let us get back to work.

Let me begin by thanking all of the witnesses who have agreed to testify today at today's hearing. Your testimony will shed light on an insidious problem about how the Medicare program reimburses health care providers for certain drugs used to treat very sick patients. Today's hearing, which is a culmination of years of investigative and audit work performed by subcommittee staff and the witnesses from our first panel, will examine how Medicare's reimbursement system for the relatively few drugs currently covered by the program is costing Medicare and its beneficiaries roughly $1 billion every year in overcharges while having an adverse impact on the health care of some of our most vulnerable elderly and disabled citizens.

We will hear how the manufacturer of a chemotherapy drug like Vincasar sold it to health care providers for $7.50, then reported the price to Medicare as $740. Medicare paid the doctor almost $600 for the same drug, and the poor sick patient got hit up for another $150.

We will also hear today from the Department of Health and Human Services Office of Inspector General about how many other overcharges result in Medicare paying more than $886 million every year in inflated prices for just a sample of 24 Medicare-covered drugs reviewed by that office. The total figure for all Medicare-covered drugs very likely exceeds a billion dollars each year.

It should be noted that Medicare currently reimburses for a very limited number of drugs, chemotherapy agents, blood-clotting factors used to treat hemophilia and inhalant drugs used to treat respiratory diseases, the total cost of which is approximately $4 billion a year. A billion dollars of taxpayer dollars is wasted every year in this program because under current Federal law and regulations, Medicare is paying for drugs at AWP. AWP, or average wholesale price, could also be an acronym for "ain't what's paid." It is quite clear that despite its name, AWP is not the average wholesale price at which these drugs are sold to health care providers or anything close to it. To the contrary, it appears that for many of these drugs, AWP is simply an artificial price established by certain drug manufacturers and reported to industry trade publications for purposes of third-party reimbursement, a price which bears little, if any, relationship to what is actually paid for these drugs by health care providers.

Before we go further, however, let us be clear about one thing. Most drug companies establish AWPs that are, in fact, fairly reliable indicators of average wholesale prices, but in those instances where they do not, the difference between what providers actually pay and what Medicare reimburses results in what is commonly re-

ferred to as a spread, an unwarranted profit pocketed by the health care provider each time he or she utilizes that particular drug. We will see evidence today demonstrating how some drug manufacturers have manipulated the reported AWPs and thus the spreads on their drugs in order to create financial incentives for providers to use their drugs over competitors' products. In doing so they have provided a financial windfall to the health care providers that enables them to sell more of their drugs. In the words of one manufacturer, this is a win-win-win situation for manufacturers, wholesalers and health care providers. The big losers in these marketing ploys are the Medicare program, its elderly and disabled beneficiaries, and the American taxpayer, all of whom have to foot the bill for greatly inflated drug costs.

Of even greater concern to America's seniors than the impact of having to pay inflated copayments on drugs based on prices that are sometimes tens or hundreds of times higher than what their health care provider actually paid for the drugs is that they also may have had the quality of their health care adversely affected by this perverse system. We will hear how the profits available for utilizing certain drugs appear to be improperly affecting some health care providers' clinical decisions, influencing them to provide unnecessary care and utilize drugs based on profit margins rather than therapeutic efficiency.

For example, we will learn of cases in which the utilization of certain drugs skyrocketed without any reasonable clinical justification after manufacturers created large Medicare-funded financial windfalls to health care providers to encourage them to use their drugs. In one such case, and the case is on the screen there, Medicare utilization and reimbursements of the inhalation drug ipratropium bromide used to treat respiratory diseases increased more that twentyfold between 1995 and 2000, from $14 million in 1995 to more than $300 million in 2001, a time period in which the drug went from having no spread to having a Medicare-covered spread of 300 percent.

We will also hear about how terminal cancer patients received aggressive courses of chemotherapy, raising questions about whether the motivation for providing such care was the profit available from the use of Medicare-covered chemotherapy drugs.

Congress has long championed the fight against cancer. We supported increased funding for research at the National Institutes of Health and to improve the quality of clinical care. We fought to ensure that the proper incentives exist to develop new and innovative drugs. To then learn of the instances in which quality of patient care might have been adversely affected by the financial benefits available to providers from utilizing certain drugs is nothing short of outrageous. While providers and their associations strongly denied being influenced by any such considerations, we cannot tolerate a system that could leave such motivations even open to question.

Providers do not generally deny that they often reap huge profits on the utilization of certain Medicare-covered drugs. Instead they argue that they currently depend on these profits in order to make up for other services in which Medicare under-reimburses them. We will hear testimony today that will confirm that like many

other groups of providers, these providers who administer Medicare-covered drugs are not fully reimbursed for all the costs associated with treating their patients.

We should reimburse all providers fairly for their expenses; nevertheless a system in which the use of certain drugs can influence clinical medical decisions is not the answer. Life-and-death decisions about the treatment of those who suffer from the scourge of cancer should be governed exclusively by a concern for the patient and not the margin of profit.

When this hearing is over, my colleagues and I will work with this new administration as well as providers and drug companies to scrap this flawed system. We will need to develop a solution that results in Medicare paying prices for drugs that are closer to the actual prices paid by health care providers. Similarly we will need to take steps to ensure that health care providers are sufficiently reimbursed for all of their services so that the quality of care they provide to the Medicare patients is not diminished by changes made to the drug reimbursement system.

I look forward to hearing from CMS Administrator Scully today about what steps his agency can be directed to take to guarantee that this scandal is resolved as quickly as and effectively as possible. In these new and perilous times when our Nation and our people may be called upon to make great personal and financial sacrifices in the defense of our country, Congress has the heavy burden of making sure that every available resource is used wisely, and if we hope to find a way to pay for an expanded Medicare drug benefit that will assist seniors to purchase prescription drugs even as we take on a renewed and determined defense of our homeland, these abuses cannot be tolerated.

If we are going to provide Medicare beneficiaries with a comprehensive prescription drug benefit, and we must, we have to stop wasting billions of dollars on the existing program. We will need every Medicare dollar we can find. In addition, our efforts to resolve this problem will hopefully serve as an example for those State Medicaid problems and other third-party payers who face similar issues in their reimbursements for the costs of drugs. This in turn could result in billions of additional dollars in taxpayers' savings beyond those amounts that were discussed above applicable only to Medicare.

There is one more important lesson in all of this. Government-run programs such as this, which escape the rigors and discipline of the marketplace, inevitably end as expensive failures. It is only by forming an honest partnership between Government and private sector that we can hope to build a new and better Medicare program on a sound financial footing.

Again, I wish to extend my thanks to all of the witnesses who agreed to appear at today's hearing to inform us about this serious problem. While I am disappointed that the invited drug manufacturers declined to testify today about these practices and how the system could be reformed, I am nonetheless committed to moving forward on this issue in a positive and productive manner with all parties so that we can fix this system quickly and protect America's Medicare beneficiaries from further financial and personal harm.

The Chair yields 5 minutes to the ranking member of the Oversight and Investigations Subcommittee, Mr. Deutsch.

Mr. DEUTSCH. Thank you, Mr. Chairman. Thank you also for your opening comments. I think for any of us not to mention September 11 would be a mistake. This is, I know, my first hearing since then, and I think for all of us on this dais, and America and the world changed on September 11, and even our work here in a sense has changed. I think if we do everything we do in our lives, I think all Americans do everything they do a little bit differently, in fact maybe a lot differently than—after September 11.

Let me mention three things and summarize an opening statement. The three things in terms of the issue in front of us that are most disconcerting, the first issue is there appears to be some evidence, and I hope it is developed in the course of the hearing, that some manufacturers, by increasing the spread on the average wholesale price, have encouraged physicians to actually do substitutions on medication. That is obviously incredibly disserving from best medical practices to best financial incentives for that individual position or office, and that is obviously a system which is fundamentally broken.

The second issue, which again is a very disconcerting issue, is that for Medicare beneficiaries, as most people are aware, their copayments are based upon Medicare reimbursements, not on the reimbursement that the physician is paying for the drug. So there apparently, again, the testimony, I think, will be brought out during the course of this hearing cases, and apparently many cases, where the 20 percent copayment is, in fact, more than the physician actually paid for the drug, and obviously the situation of Medicare beneficiaries, that is an absolutely absurd situation.

As we develop this—and this is part of the problem, and I am looking forward to testimony about this as well—is we have a situation where we have a reimbursement system which I don't think anyone can honestly defend in terms of the average wholesale price, but I think we also have a reimbursement system on the physicians' side that is hard to defend as well. Obviously these two things are related. I guess there is debate about how related they actually are, but I think that we need to acknowledge that, and we need to do our part in terms of fixing it.

I have a lengthy statement, which I think at this point, based on the time, I would rather submit for the record. So I will submit that for the record as well as Mr. Dingell has a statement and the chairman of the Ways and Means Committee, Mr. Stark, also has a statement that they were going to submit for the record as well.

[The prepared statement of Hon. Peter Deutsch follows:]

PREPARED STATEMENT OF HON. PETER DEUTSCH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Thank you, Mr. Chairman, for holding this very important and long overdue hearing. For many years, the Inspector General of the Department of Health and Human Services—like a voice crying in the wilderness—has been issuing reports telling the Department and the Congress that the taxpayers were being gouged for drug payments under both the Medicaid and the Medicare programs. These federal programs were paying providers the published Average Wholesale Price or AWP for prescription drugs which was, in truth, far more than the drug manufacturers were charging them. The program now has spun so far out of control that the annual overpayments may be as high as $1.9 billion. We will hear testimony today of a

scheme where doctors prescribing drugs to be administered in patients' homes wanted a kickback from the infusion companies based on the AWP spread over actual cost. The Justice Department and numerous states have been investigating this situation, and hundreds of millions of dollars have been recovered.

Only Congress and the reimbursing agency have been silent. In fact, we—particularly those on the other side of the aisle who are concerned about anything that they think might resemble setting prices—have stopped almost every reform effort. We must take steps now to eliminate this abuse.

Over the years, Medicaid at both the federal and state levels has been able to get a 15 percent discount from the AWP plus a rebate from the manufacturer that can reach up to another15 percent based on the reported Average Manufacturers Price or AMP. But drug manufacturers, the Medicare carriers, the Centers for Medicare and Medicaid Services (CMS) and its predecessor, the Health Care Financing Administration, or HCFA, the Congress and the providers have all combined to establish, further and abuse the fraudulent Medicare drug reimbursement system. The drug companies—who, Mr. Chairman, are notable by their absence at this hearing since they *were*, I believe, the instigators of this scheme—reported artificial and false Average Wholesale Prices to the public for reimbursement purposes while at the same time *not one* of their customers was paying those prices.

The Medicare carriers paid those prices and failed their responsibility to assure that actual drug prices were being paid. HCFA tried to reform the system, but often gave up because of provider objections. Congress and the Executive branch also aborted HCFA's reform attempts by citing the Paperwork Reduction Act and requiring reports from the General Accounting Office before any changes could be made. The reports we are receiving today are the most recent mandated by Congress in place of real action.

As we will hear in testimony today and is verified by the documents to be placed into the record, the pricing abuses have reached the point at which drug manufacturers use the "spread" between the AWP and the actual price paid as a marketing tool to sell their products. Not only does the taxpayer get gouged; so does the Medicare beneficiary who is required to pay 20 percent of the total cost of the drug. A chart prepared by one of the witnesses provides *nine* examples in which the 20 percent copayment covered the entire cost of the drug to the provider. A breast cancer treatment costs the provider $450; it charges Medicare $1,359. The co-pay is $272; the profit is $909.

Some of the providers of out-patient drug treatment that we will hear from today will say that they are using these excessive payments to cover their treatment costs in other areas. They allege that they will not be able to continue providing service if this is not remedied. If that is true, their arguments and those of other specialities suffering from similar under payments should be documented and presented to CMS. However, there is a pilot Medicare drug program in Texas underway in which competitive drug pricing is used. The costs are down, and there is no evidence of the withdrawal of any providers. We must also remember that the General Accounting Office has found a number of times that there is little or no evidence of underreimbursement of providers under either Medicare or Medicaid.

Mr. Chairman, I look forward to hearing from these witnesses.

Mr. GREENWOOD. Without objection, all members' opening statements will be submitted for the record.

The Chair recognizes the chairman of the full committee, the gentleman from Louisiana, Mr. Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman.

Mr. Chairman, I, too, want to thank you for the moment of silence for the recognition of Lisa Raines and the loss of so many friends across America, but also your determination to move forward with this important hearing, and I want to congratulate the staff who worked with you to develop this hearing, which I believe will highlight one of the most important abuses within the Medicare system that this committee has ever uncovered.

What you will see today is a situation that has turned Adam Smith on his head; a situation which, because of the system in which we reimburse physicians for the cost of certain drugs particularly in chemotherapy and inhalants and several other categories, but the Government of the United States is paying in some

cases many times the price that the physician is actually buying the drugs for. Worse than that, worse than this loss of billions of dollars of Medicare dollars that taxpayers put up to make sure that our mothers and fathers and grandmothers and grandfathers and all our relatives are properly cared for in the Medicare health system and in the Medicaid system, by the way, worse than this loss of the funds that are critical to sustain the program is the fact that the patients, those loved ones we protect under this system, are being required under this system to put up not 20 percent of the cost of the drugs to the doctor, but in one case—and I have a chart I want to show you up there, the Medicare 20 percent copay chart—in one case with a drug called Doxorubicin, the patient is putting up not 20 percent, but 200 percent of the cost. The patient who is supposed to put up 20 percent is putting up 200 percent of the true cost of the drug.

Look at the drug etoposide. In that case the patient is putting up not 20 percent, but 300 percent of the cost, triple the cost the doctor spends on the drug. The poor Medicare patient ends up tripling his contribution for the total cost of that drug instead of putting up just one-fifth of the cost.

Look at the drug Leucovorin. It sounds like a character in The Godfather, maybe properly named. In that case the Medicare patient is putting up 500 percent of the cost of the Medicare drug as a copay.

Look at the column of the Florida Medicare allowable. Look at what the doctor is getting back from the Medicare system in Florida for those three drugs. The doctor is paying for Leucovorin $1.25 for 50 milligrams, and the patient is putting up $7.09, and the Medicare system is paying the doctor up to $35.47. That is the spread we have been talking about. The spread between the real cost of the physician and the cost the Medicare system is paying for the drug, and perhaps the copay cost the poor patient has to put up, in some cases as high as 500 percent of the real cost of the drug to the doctor. How can we tolerate such a system any longer?

Mr. Chairman, I really appreciate your uncovering this and allowing this hearing literally to go forward when I know most people are concerned about us getting back to work too fast. We have got to get to work on this one fast. Not only does this rob the Treasury and the Medicare fund of billions of dollars that should not be paid because they are not the average wholesale prices, they are some kind of awful artificial wholesale price, but, again, it turns Adam Smith on his head.

Think about this with me for a second. We introduced generic drugs into the system to create competition. Do you know what happens to the system when a generic drug comes into play? Evidence we have that we will develop today indicates that when a generic drug comes into competition with a patent drug finally, the price doesn't come down. The price goes up because both of the drug companies understand that if they are going to sell that drug to the doctor, they have got to give them a bigger spread. So they are in competition to give them a bigger spread, and they both post higher and higher artificial wholesale prices to the Medicare system.

It is a game that turns ordinary economics on its head. As competition comes into the field, prices go up not only to the government, but to the poor patient who has to pay not 20 percent, but 300, 400, 500 percent of the cost of the drug. It is a rotten system.

And, Mr. Chairman, perhaps the most pernicious part of it all is the evidence you uncovered with our staff that indicates that—at least some evidence that in some cases chemotherapy may be dumped into patients in the last 3 years of life because there is so much profit to be made. There is so much profit to be made on some of these drugs, when that chemotherapy just literally rips up bodies and the welfare of those patients in the last 3 months of their life, maybe chemotherapy that might not be needed. Maybe drugs are being substituted when a better drug is available because the drug substituted has a better kickback, if you will.

Now it is time the system be reformed, Mr. Chairman. I want to thank you and the staff for uncovering it as much as you have. If there was one thing certain about this, it is that the responsibility lies in this Congress to straighten it out. We permitted this to happen. We have got to straighten it out. And I have asked you to do one thing before you went forward with this hearing, and that was to be prepared to straighten it out; not just to talk about it, not just to make Americans understand how rotten the system is and how all the players in it hate it as much as I hope we all do now, because we are all forced to play this ugly game with one another, but more importantly you are prepared to cure it. You and Mr. Bilirakis, the chairman of our Health Subcommittee, are prepared to offer solutions not next year, but immediately, and I think every patient in America who is getting skinned by this system to the tune of 500 percent of the real cost of the drug when they ought to be paying one-fifth of it, I think they will thank you today for doing the Nation a real favor by getting rid of a system that robs the American taxpayer, the Medicare system, corrupts the system, deprives patients of their critical dollars at a time most needed, and in some cases may encourage the few, I hope, unscrupulous people to improperly medicate people in their worst hours, in their last final hours on this Earth.

I yield back the balance of my time.

[The prepared statement of Hon. W.J. "Billy" Tauzin follows:]

PREPARED STATEMENT OF HON. W.J. "BILLY" TAUZIN, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Let me begin by thanking Subcommittee Chairmen Greenwood and Bilirakis for holding this joint hearing today. I appreciate their efforts to highlight the problems that this Committee has uncovered concerning Medicare drug prices. I sincerely hope that, by holding this hearing, we can begin the process of fixing these problems.

As Chairman Greenwood has pointed out, the Committee has uncovered disturbing evidence that Medicare may be wasting over one billion dollars a year, paying unnecessarily inflated prices for drugs. This intolerable situation not only affects the finances of the Medicare program and the American taxpayer, but also directly impacts the finances of America's Medicare beneficiaries.

We all have parents, grandparents, friends, or neighbors who depend on Medicare to help them pay for the small number of drugs that Medicare currently covers. It is unacceptable that—because of the government's ineptitude in the way it pays for these drugs—our loved ones are being forced to pay inflated co-payments for their chemotherapy drugs to cure their cancers, inhalation drugs to treat their respiratory diseases, and antibiotics to treat their infections.

The Inspector General's Office at the Department of Health and Human Services recently prepared a report for me that shows how, last year alone, Medicare beneficiaries paid an extra *one hundred and seventy seven million* dollars in co-payments due to inflated reimbursements for Medicare-covered drugs. For example, this means that cancer patients are paying an extra $6.56 for each dose of Doxorubicin, and an extra $3.01 for each dose of Leucovorin Calcium. These costs quickly add up in treatment regimens requiring multiple doses, and often can make an enormous difference for somebody living on a fixed-income.

Of even greater concern to me is the evidence uncovered by the Committee indicating that these overpayments to health care providers may be affecting the quality of care received by Medicare patients. Patients may not be receiving the most clinically effective treatments, due at least in part to the perverse incentives of the Medicare reimbursement system. The Committee has learned of instances in which the Medicare reimbursement "spreads" on certain older, less clinically effective drugs were so large that drug manufacturers were unable to successfully market improved, more clinically effective drugs to health care providers.

The Committee also has learned that some patients may be receiving unnecessary medical therapies—again due at least in part to the excessive reimbursements available to health care providers for use of certain drugs. Given the powerful effects that these drugs can have on patients, we must ensure that no patient receives a particular drug regimen for any reason other than to provide the best clinical care.

Medicare's broken reimbursement system also turns Adam Smith's conception of market competition on its head. Only under Medicare could a drug manufacturer *raise* its prices, or at least the ones it reports for purposes of government reimbursement, to increase sales. The Committee has uncovered evidence that at least one manufacturer has done exactly this. Upon learning that a competitor raised its reported Average Wholesale Price and thus its Medicare reimbursement spread, this manufacturer responded promptly in the same fashion, noting how simple it was to change its AWP—something that could be done overnight—in order to maintain sales.

Here's another example of this crazy AWP system at work: an internal drug manufacturer document from 1994 discusses the consequences of increasing the spread on one of its top drugs, quote, "in order to increase the amount of Medicaid reimbursement for clinical oncology practices." In a particularly blunt assessment, the author notes with irony how, quote, "on the surface, it seems that in response to the entrance of a competitor in the market, Glaxo has actually raised its price on Zofran—perhaps twice in one year." The memo goes on to ask: "How do we explain a single 9% increase in the AWP? What arguments can we make to explain to congressional watchdogs that we are cost-shifting at the expense of government?" Despite recognizing the troubling issues raised by such a pricing strategy, Glaxo succumbed to the system anyway, raising its Zofran AWP two months later, while actually lowering the real costs of the drug to providers.

Medicare also distorts the benefits of the generic drug market. Generic drugs hold the potential to decrease pharmaceutical costs dramatically, through price competition with brand-name drugs. Under Medicare, however, the Committee has uncovered situations in which some generic manufacturers competed for market share by *raising* the prices they reported to the government—thus increasing costs to taxpayers and patients—while actually selling the drugs to providers at steep discounts.

Today's hearing will highlight these abuses. It is my hope that, by bringing this information to the attention of Congress and the American public, we can build support for reforming the currently flawed Medicare drug reimbursement system. Chairmen Greenwood and Bilirakis should be commended for their role in this effort, and I look forward to working with them and all the Members of this Committee in solving this problem. I believe that Medicare's beneficiaries and America's taxpayers deserve no less.

Mr. GREENWOOD. I thank the gentleman for his comments and cooperation and support in this project and inform the chairman that it is our intent to have legislation included in an omnibus—whatever omnibus appropriations bill is finally adopted by the Congress that will fix this system soon.

The statement of the ranking member of the full committee has been entered into the record, and with that the chairman then turns to the ranking member of the Health Subcommittee for 5 minutes.

Mr. BROWN. I thank the chairman. I thank both Chairman Bilirakis and Chairman Greenwood for holding these hearings.

A recent poll conducted by Pew Research Center told us that Americans are finding it difficult to reengage in their daily lives after the heart-breaking events of last week. We certainly didn't need a poll to tell us that. I think most people in this room are struggling, as all of us up here are, to regain our footing and return to their lives despite the anger and sense of loss that has paralyzed in some sense many of us. But I think most of us also feel it is time to get back to work.

Staggering prescription drug costs are still pushing retirees deeper into poverty. Forty-four million Americans are still uninsured, and that number pretty clearly is rising. The uncertain economic climate makes it more important than ever to fortify the Nation's core public programs, Medicare, Social Security, Medicaid, our public health infrastructure.

Our job today is to look at some shady dealings between drug companies and the Medicare program. The Medicare program and Medicare beneficiaries are being scammed to the tune of $800 million annually. Some drug companies mark up their prices before reporting those prices to Medicare. What do the drug companies gain from this deception? They gain a higher volume of sales. What do doctors gain from this? They gain a healthy margin in the drugs they administer to Medicare beneficiaries. What do Medicare beneficiaries gain? They gain significantly higher out-of-pocket cost when the copayment is artificially inflated. Medicare pays more than it should, Medicare beneficiaries pay more than they should, and doctors not only receive higher reimbursements than they should, they have an incentive to overtreat patients. There is evidence that a few doctors actually take the bait and administer more medication than is necessary.

When you think about the type of drugs Medicare currently covers, chemotherapy, immunosuppressives, respiratory therapy drugs, other medications for serious, serious illness, it is truly disturbing to think that any doctor would compromise the Hippocratic oath in this manner. On the face of it, the so-called average wholesale price scam looks like a textbook case of fraud, waste and abuse. AWP is a bit like the Holy Roman Empire we learned about in school. The Holy Roman Empire to be sure was not holy, and it wasn't really Roman, and you could hardly call it an empire. It is the same with the average wholesale price. They aren't the average of anything, they certainly aren't wholesale, and, in fact, they aren't even prices. They are a marketing tool.

Unfortunately in some cases the excess Medicare spending appears to compensate for inadequate Medicare reimbursement. That makes the job of this subcommittee or both subcommittees and this committee more difficult. Not only do we have to figure out how much to pay for these drugs, we have to figure out how and how much to pay providers who are not receiving adequate reimbursement for administering these drugs.

But there are also opportunities here. When we look at how to pay appropriately for this limited set of prescription drugs, we should also think about how to pay appropriately for all prescription drugs. We can tell that the prices Medicare pays are artifi-

cially inflated across the board, in the majority of cases are artificially inflated, by comparing them to the prices other U.S. Purchasers, large HMOs, the VA, certain big hospitals that other U.S. Purchasers pay. We can tell that the drug prices that American consumers pay are artificially inflated by looking at the prices consumers in other countries, in other developed wealthy countries, pay.

Consumers, employers, and other purchasers in the United States pay two, three, sometimes four times more than their counterparts in every other developed country in the world for prescription drugs. As a Nation we are the worst equipped to weather artificially inflated drug prices. Every other developed country has universal health insurance. We have 44 million uninsured individuals under age 65. We have 12 million Medicare beneficiaries who have no prescription drug coverage.

Mr. Chairman, we have a lot of work to do. Thank you.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for his opening statement the chairman of the Subcommittee on Health, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I, too, would like to thank you for raising and staying with this issue surrounding this current system of Medicare drug reimbursement which has resulted in this joint hearing. The Health Subcommittee has spent a considerable amount in this Congress examining how best to add a comprehensive prescription drug benefit to the Medicare program. This hearing builds off the work that began in the last Congress where we examined the reimbursements for the limited drug coverage currently available in the Medicare program.

I would like to welcome and thank our witnesses, including Tom Scully from CMS and Bill Scanlon from GAO. We rely on these government officials for factual information and detailed analyses. I also would like to welcome Mr. Zachary Bentley from my home State of Florida, the southern part, and I know your testimony, Mr. Bentley. All the witnesses will help inform the committee and the public about the issues regarding Medicare's current reimbursements to health care providers for certain drugs used to treat patients.

The Medicare program currently provides coverage for a small number of drugs, as we know, much too small, but a small number, limited principally to those that are administered incident to physicians' treatment or in conjunction with covered durable medical equipment such as inhalation drugs used with a nebulizer. Since at least 1992, Medicare has determined the appropriate reimbursement price for these covered drugs by referring to an industry trade publication known as the Red Book, which looks at what manufacturers purport to be the average wholesale price for their drugs. Since 1977, providers who administer these drugs to Medicare beneficiaries have been reimbursed for their cost at prices equal to AWP, average wholesale price, minus the 5 percent. Of this set amount, Medicare Part B covers 80 percent—this has all been said, I realize—while Medicare beneficiaries can be required to pay the remaining 20 percent as copayment.

Today's hearing will examine how Medicare's current reimbursement system for the relatively few drugs that are covered is costing

beneficiaries and taxpayers more than is necessary and maybe having an adverse impact on the health of some of our most vulnerable citizens.

I recently toured, Mr. Chairman, Clearwater Oncology Center in my Florida district, and I am sure we are all aware of what great work oncologists do and how important they are to us and just to all Americans. At the request of my constituent Dr. Marcus Chopart, I would like to admit this white paper prepared by U.S. Oncology, which is entitled Reimbursement Versus Reality, into the record and ask unanimous consent for that.

Mr. GREENWOOD. Without objection.

[The following was received for the record:]

REIMBURSEMENT VS. REALITY

A US ONCOLOGY DISCUSSION PAPER ON MEDICARE PAYMENTS FOR CANCER TREATMENT

Introduction:

Today, the Medicare program makes a significant and well-recognized overpayment for oncology drugs. The program also makes a nearly equivalent but less well-recognized underpayment for practice expenses associated with the delivery of cancer care. This paper is intended to discuss the causal factors and current experience of this practice expense underpayment. It is offered in the hope of furthering the public policy discussion and the cancer community's longstanding support for balanced reform, which will address Medicare's overpayment of drugs and underpayment of services. In this manner, the Medicare program will provide a stable source of adequate reimbursement for cancer care supplies and services and preserve patient access to community-based cancer services.

Discussion:

Medicare practice expense reimbursement for chemotherapy administration was established to accommodate a delivery system profile that no longer exists in the US. Whereas most chemotherapy was administered in hospital settings as recently as the late 1980s, Centers for Disease Control and Prevention (CDC) data currently indicate that more than 80 percent of all chemotherapy treatment encounters occur in non-hospital outpatient settings (freestanding oncology physicians' offices and community cancer centers). Reimbursement policy changes, managed care cost-saving pressure, patient preference, the advent of more effective ambulatory therapies, and the advanced capability of freestanding facilities to provide highly-complex care are the major causal factors that fueled the migration of patients from hospital to non-hospital settings.

This historical perspective is important because it helps to explain the flaws plaguing the Medicare program's practice expense reimbursement policy for cancer care. When the Resource-Based Relative Value Scale (RBRVS) was established in 1992, the Practice Expense (PE) components within the RBRVS were based upon historical "usual and customary" physician fee schedule systems that evolved at a time when most chemotherapy was administered in hospitals. As a result, reimbursement levels for the RBRVS codes relating to physicians' offices and other freestanding facilities were based on the few resources that were used in those settings during the period preceding the RBRVS implementation.

The evolution of cancer care and the resulting reimbursement discrepancy described above has long been recognized by Congress and HCFA/CMS. For example, after it became clear in the mid-1980s that chemotherapy was moving to freestanding facilities, Congress required the Secretary (in section 4055(d) of OBRA 1987) to study and report to Congress on possible Medicare reimbursement changes to more accurately reflect the costs associated with providing chemotherapy in physicians' offices. HCFA subsequently published a notice in the Federal Register that recognized that Medicare payment for chemotherapy administration may be inadequate:

> "Changes in treatment methods and advances in technology now allow chemotherapy to be furnished to many patients in the physician's office, thus reducing the need for hospitalization to administer chemotherapy. Furnishing these services in the physician's office is more convenient for some patients and may provide other benefits as well.

"Current Medicare Part B payment rules for physicians' services, however, may fail to compensate adequately for these services because the usual reasonable charge methodology may not fully recognize the overhead costs involved in these procedures. Some sources of additional costs include employment of nurse oncologists, special patient rooms, and safety equipment required because of the toxicity of the chemotherapeutic agents and safety procedures issued by the Occupational Safety and Health Administration."

Unfortunately, this recognition has never been translated into more accurate Medicare reimbursement for cancer care services. As a result, inadequate and inaccurate payment levels have been utilized since the creation of RBRVS, with updates for inflation but without any significant revision, even though the locus of non-surgical cancer care has moved from hospital settings to freestanding physicians' offices and community cancer centers.

In other words, the resource-based codes currently used by Medicare to reimburse for oncology practice expenses do not reflect the transfer of resources from hospitals to freestanding facilities and the additional costs that have arisen consistent with advances in and the complexity of today's more effective treatment regimens. Put another way, hospital care and complex services moved to freestanding facilities—but Medicare's practice expense reimbursement policy has never been significantly and continuously updated to reflect that fact.

Summary Points:

The implications of the above can be identified through examination of the many instances of shortfall which exist between the delivery and reimbursement of cancer care in freestanding facilities. The following bullet points summarize just a few of these:

- Today, nursing and pharmacy time comprise the principal components of the direct labor costs of oncology practice expenses (PEs). However, the allocation of values and minutes within the CPT codes does not match the actual cost and duration of nursing services and does not address pharmacist and pharmacy technician labor and related medical supplies and quality control processes. For example, CPT 96410 (first hour of chemotherapy infusion) does not adequately reimburse for the actual costs of the activities which currently fall under the definition of that code. In addition, activities which need to be performed in the care of a typical patient often exceed 96410's 121 minute estimate of total nursing time. This is a commonplace problem in oncology due to:
  - The compromised physical and mental condition of many seniors with cancer,
  - The complex procedures integral to the care provided to all cancer patients undergoing chemotherapy treatment (for example: patient assessment prior to chemotherapy administration, evaluation of laboratory data such as blood counts and renal and liver functions, calculation of drug dosages based on body surface areas to prevent medication errors, insertion of intravenous or central venous catheter devices, continuous monitoring to address potential adverse reactions, a variety of assistive care activities, and hazardous materials preparation and disposal).
  - The amount of patient and family member training required due to the delivery of outpatient rather than inpatient care, the complexity of care provided, and the side effects and potential complications associated with multi-drug agent chemotherapy regimens,
  - The time-intensive nature of patient care-related follow-up and monitoring required due to the life threatening side effects and complications routinely experienced by cancer patients during a typical chemotherapy protocol, and
  - The recently-established standard of practice in which pharmacists and pharmacy technicians are utilized within cancer care facilities to enhance the safety of the drug administration process. As the recent Kansas City experience clearly demonstrates, on-site skilled pharmacy services are integral to the delivery of safe and effective cancer care.
- Medicare utilizes chemotherapy administration codes published in the AMA's *Current Procedural Terminology* (CPT) manual but applies rules that differ from the CPT's descriptions. For example:
  - Medicare only allows code 96408 (administration by push technique) to be reported once per day for a patient regardless of the number of drugs administered by push. Many treatment regimens require the administration of multiple drugs, however, some of the most common of which are vesicant. Drugs classified as vesicant are agents that will cause serious tissue damage (including potential loss of limb) if they leak into the tissues of the patient's hand or arm; as a result of the potential for this serious complication, the administration of vesicant drugs requires prolonged one-on-one nursing care. As a re-

sult, caregivers routinely bear significant multiple push and specialized care costs that are not adequately reimbursed under current practice expense policy.

- CPT 90784 (intravenous push of therapeutic medication) is a code that was established to cover the costs of administering non-chemotherapy agents such as anti-nausea medications, anti-sensitivity drugs, and steroids. Despite the intention that code 90784 provide reimbursement for therapeutic agents and despite the fact that such agents are often a necessary component of a chemotherapy regimen, Medicare will not make a payment for 90784 activities that are undertaken on the same day as the infusion of a chemotherapeutic agent.

  CPT 96410 includes a general description of the service (first hour of chemotherapy administration). Based upon that description, CMS' Clinical Practice Expert Panel (CPEP) process has estimated a time allotment of 121 minutes, an allotment included in published Medicare payment policy. However, actual Medicare reimbursement does not currently cover 121 minutes of nursing time and instead provides for a payment level that covers just an estimated 20 percent of costs associated with 96410.

- Current Medicare practice expense reimbursement for oncology either does not take any account of a wide variety of activities which are common and integral to the delivery of cancer care in freestanding facilities or allocates significantly insufficient minutes and resources to them. For example:
  - Triage and patient/family education, which consumes an estimated 25-40 percent of a typical oncology nurse's day (versus the 15 minutes now allocated by Medicare) and involves frequent and lengthy phone interaction with the patient and/or the patient's family support person,
  - Tumor registry-related activities (required by most state health departments and managed by the Centers for Disease Control and Prevention),
  - Clinical research-related activities (recently approved for Medicare coverage but currently lacking any PE adjustments for the significant labor adjustments required due to the data intensive nature of the clinical research process),
  - On-site pharmacy-related activities (increasingly becoming the standard of practice due to the increasingly complex nature of new chemotherapy drugs and biotechnology agents and due to the necessity to free up oncology nurse time in light of the national shortage of trained nurses),
  - Biohazardous waste disposal (including federally-mandated disposal systems and required monitoring of disposal by specialized vendors in federally approved disposal sites), and
  - Financial counseling and financial aide assistance (requiring an estimated 10-20 percent of a typical oncology nurse's day due to the aggressive denial of benefit standards-of-practice within the insurance industry and by Medicare intermediaries).
- As a result of the scope of services that are not currently being reimbursed or that are inadequately reimbursed, oncology nurses estimate that a majority of their time is devoted to activities that are not currently "billable" (i.e. considered within the components of the various CPT-4 codes) under Medicare. Of those activities which can be billed today, the vast majority are reimbursed at levels that are far below the actual cost of undertaking them (at levels estimated to be less than 20 percent of actual costs reimbursed).
- Current Medicare practice expense reimbursement for oncology does not take into adequate account a wide variety of processes, supplies and equipment which are common, frequently mandated by federal law or regulation, and integral to freestanding facilities. For example:
  - Hepa-filter equipped hoods for admixture (to prevent exposure and contamination),
  - Safe-needle systems (to prevent caregiver needle sticks),
  - Biohazardous waste containers (to prevent exposure and contamination),
  - Reinforced gowns and gloves (to prevent exposure and contamination),
  - Specialized devices required to access implantable central venous ports to safely administer toxic chemotherapeutic agents and reduce the complications (especially life threatening infections) associated with frequently repeated intravenous drug administration processes,
  - Business and clinical record audits and internal reviews required to ensure compliance with billing regulations as recommended by the OIG Guidelines For Medical Practices, and
  - Business and clinical record audits required by the FDA, OIG, and Medicare intermediaries associated with standard of care procedures and drugs utilized in the clinical research process.

- In the late 1990s, Medicare practice expense components were made resource-based, a process which presented an opportunity for the inadequacy of drug administration payments to be addressed:
  - HCFA initially pursued an approach that would have increased payments to cover costs; the Agency adopted a "bottom up" approach under which clinical practice expert panels (CPEPs) were formed to estimate the staff time, supplies, and equipment used in each service.
  - Because the bottom up methodology would have resulted in significant shifts of Medicare payments among various specialties, however, legislation was enacted that postponed implementation of the resource-based practice expense components for one year and specified new criteria for HCFA to consider in adopting a methodology.
  - As a result, HCFA changed to a "top down" methodology, which resulted in the preservation of the status quo.
- On November 1, 2000, HCFA published the final rule for the FY 2001 physician fee schedule that also presented an opportunity for the inadequacy of drug administration payments to be addressed:
  - HCFA accepted and published recommendations made by the American Medical Society's Relative Value Update Committee (RUC) and Practice Expense Advisory Committee (PEAC) for CPT codes 96408 and 96410. [42 CFR Parts 410 and 414, 65392-65393]
  - In its rule, HCFA stated "We will now use the RUC-recommended total times of 102 minutes of clinical staff time for CPT code 96408 and 121 minutes for CPT code 96410." HCFA also posted a complete database on its website (http://www.hcfa.gov/stats/resource.htm) that provided dollar values (inclusive of direct and indirect expenses) for the updated codes, as follows:

Code	Published Value	Actual Value	Percent Difference
96408	183.67	37.11	495%
96410	267.05	59.684	47%

  - Despite being accepted and published by HCFA in its final rule, the significant increases were not adopted into the Medicare program's actual payment levels.
- For codes lacking a physician work value (such as all chemotherapy administration codes), HCFA adopted a methodology in which a special "zero work value pool" was created. HCFA has never published an explanation of this methodology, but the pool reportedly is assigned dollars based on the practice expenses per hour of the average physician, and non-physician time for each procedure is substituted for the physician time that would otherwise be used.
  - As a result of this methodology, Medicare payment amounts were kept at approximately the same levels as existed prior to the institution of the resource-based system (in fact, it has been suggested that HCFA selected this methodology to maintain the status quo in payment amounts).
- Medicare pays a "bad debt credit" to offset uncompensated care provided by hospital settings but does not currently have any provision for such a payment to freestanding facilities (which provide the majority of uncompensated chemotherapy services to Medicare beneficiaries who cannot meet their coinsurance obligation, among other needy patients).
  - According to the Medical Group Management Association (MGMA), the typical physician office setting experiences a non-collection rate equivalent to 7.5 percent of allowable reimbursement.
  - In many community-based cancer care facilities—where a large segment of the Medicare patient population is dependent upon Social Security as a main source of income—non-collection levels may be much higher than MGMA's estimate.
- A number of activities and infrastructural resources are needed to operate an efficient and compliant oncology office. However, many of the costs associated with those activities and resources are not currently reimbursed. As a result, additional practice expense allotments or reasonable returns on services, products, and other resources are needed to: attract and retain staff (due to the inadequacy of current practice expense reimbursement); invest in facilities, therapy inventories, and required diagnosis and treatment technology; finance accounts receivable; invest in information and operational systems to meet NCI/FDA clinical trial research data requirements; retain outside compliance advisors and auditors; and meet HIPPA regulatory requirements.

Conclusion:

It is our hope that this information will be helpful as Congress and the Administration seek to address the disparity between typical, necessary practice expenses and the reimbursement currently provided under the Medicare program (and, as a consequence, by private payers). It is also our hope that a clear focus on the nature, complexity, resource intensity, and technological advances of community-based cancer care—as well as the reliance by the vast majority of Americans with cancer on care provided in community-based settings—will lead to an updating of Medicare practice expense reimbursement to accurately reflect the realities of cancer care delivery today.

Mr. BILIRAKIS. This will prove to be a lengthy hearing, and thus I am limiting my opening statements so we may get to the important testimony of the witnesses, who, again, I thank for their efforts and cooperation. Thank you, sir.

Mr. GREENWOOD. I thank the gentleman and thank him also for limiting his remarks. I will ask if the opening statements of the Members could be limited to 3 minutes, and all opening statements will be entered into the record.

The Chair recognizes for the opening statement the gentleman from New Jersey Mr. Pallone.

Mr. PALLONE. Thank you, Mr. Chairman, and I want to thank you both, you as the Oversight Chairman and also Mr. Bilirakis as the Health Subcommittee Chair for holding this hearing.

The issue on the table today critically analyzing the marketing practices of drug companies will show the immense amount of fraud perpetrated on the taxpayers and the senior citizens of this country. I along with all of my colleagues condemn practices that raid the Federal Treasury of at least $800 million annually. Further, I am particularly outraged at the impact of this pervasive fraud on Medicare beneficiaries by massively increasing the dollars coming out of pocket to cover the drug costs of sick and dying seniors as a result of the 20 percent copay overcharges.

Mr. Chairman, the GAO, the HHS, inspector general, and some particularly well-informed whistleblowers will testify today and leave no doubt that this system is broken and that the people who can least afford the cost, our seniors, are the primary victims.

Let us take a look at the winners and losers in the way HCFA pays for the few outpatient drugs that Medicare covers under Part B. The winners are obvious. They are the brand name drug companies and some unscrupulous physicians that administer the chemotherapy and other infusion drugs in their offices. There have been some discussions that generic competition is the cause for the broken system, but make no mistake, it is not independent generics, but rather the brand name firms that are the root cause of this fraud.

The companies named publicly in news stories as having pled guilty to crimes are under active investigation. In addition, Mr. Chairman, the competition is not always among drugs that the FDA says are generic equivalents. The competition is also among brand name drug companies that go to great pains to claim that their products are not therapeutically interchangeable.

Documents which will be introduced at this hearing will show that the salesmen peddling these drugs were not arguing that their medicine was therapeutically superior to the competition, but rather the internal company documents make clear the field of battle

was who could misrepresent their prices more outrageously to Medicare so as to provide the fattest profit. There are some greedy doctors, of course, who pocket sums approaching a million dollars, and they are obviously making a lot of money; however, it is the drug companies' fraud that makes the money possible.

The Medicare reimbursement system is flawed, clearly, but no law, no regulation, no guideline issued by HCFA or any other government agency directed drug companies to commit fraud. Just because a system can be gamed doesn't provide any person or any firm with the right to defraud the government or their fellow citizens, and the proof of that is that not all drug companies played this game. Some chose to compete only on traditional terms, and I certainly commend them for that. Unfortunately, at least in segments of the market, the honest firms were the exception and not the rule, and I find that very tragic.

Thank you very much, Mr. Chairman.

Mr. GREENWOOD. I thank the gentleman and recognize the gentleman from Florida Mr. Stearns for his opening statement.

Mr. STEARNS. I thank the chairman, and I also want to thank Mr. Bilirakis for all the work he is doing on this hearing, too. And, of course, I want to thank Administrator Scully for coming here with Deputy Inspector Grob and Director Scanlon for their dedicated analysis. And perhaps this is a quagmire that they can help us out of by suggesting legislation, what we should do.

This is sort of an embarrassing thing to be here, this many people. Obviously when I see a lot of people like that, there are pocketbooks involved here, but we have got to do something, and as Chairman Tauzin mentioned, we cannot sit here and let this continue. I almost think there is moral obligation to go back and try to rectify this. No one is talking about all the American citizens who have paid all this money and have paid too much, and it is out of their pockets, and it has gone in the wrong directions, and it is difficult to go back in retrospect and try to come back with something to rectify this but just move forward. Maybe that is all we can do.

I also want to thank Mr. Zachary Bentley from my State of Florida. I know it is a little difficult for him to come up here with airline travel, so I appreciate his efforts in coming up here.

This is a very thorny question, reimbursing for drugs. Who would have thought that when Medicare started, that you would actually be doing a lot of the caring for patients in outpatient clinics? I had the opportunity to visit and to tour an oncology center in my hometown of Campbell, Florida, and it is very satisfying to see patients cared for in this outpatient clinic. The drugs are administered by nurses and doctors, and these patients have their family right there. It is an informal situation, but all the while this is happening and they are administering these drugs and taking care of them, obviously the question they brought to my attention is that Medicare is overpaying for drugs, but underpays for services associated with the administration of therapies. So this is a very poor accounting practice.

It is immoral what we are doing. It is unsettling to patients, and many patients, as the chairman has pointed out, are paying 300 and 500 percent in their copayment. This cannot be tolerated, and,

Mr. Chairman, I commend you for your hearing today, and your commitment to do legislation is very important.

Finally, it is hoped that whatever drug reimbursement system is employed, it should not impose burdensome accounting requirements on the medical facilities and providers. So whatever we do, let us try to rectify the problem without creating another overlay of government upon government with some kind of accounting procedure. Remember, the caregivers who take care of patients with cancer and all these respiratory problems and devastating illnesses are healers. They are not bean counters. They don't want to spend the rest of their life filling out government forms to rectify this problem.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentlelady from California Mrs. Capps.

Mrs. CAPPS. Thank you, Mr. Chairman.

Obviously for most of us our thoughts are elsewhere today. They are in New York, at the Pentagon, in the homes of the families across America who have lost loved ones in last week's terrible events. I think especially of Lisa Raines, so closely involved with many in this room today. Those events and their ramifications will certainly be with us for a long time, and clearly we need to spend significant time on our Nation's many responses to them.

But I am very pleased that at this time this committee is making an effort to continue its business. Although the attacks have changed many of our priorities, we still must address Medicare and Medicaid and other issues that may seem mundane in comparison.

So I want to direct my attention to the issue at hand. It is very disheartening to learn about efforts to take advantage of our Nation's seniors and America's taxpayers. And clearly if what we have been told is true, that is what has happened. Pharmaceutical companies have worked to increase their profits by artificially raising the Medicare reimbursement rates for certain prescription drugs, particularly oncology drugs. Sometimes this happens to the point where our beneficiary pays more in his or her copayment than it costs to buy the drugs outright. Clearly, given the current budget situation, Medicare cannot afford to be paying too much for the services and prescription drugs, and certainly our seniors are already too strapped to afford most of their prescription drugs. To take money from their already overextended pockets this way is terrible.

It is even worse that this is being done with something as important as oncology drugs. People suffering from cancer should not be the target of anyone trying to make a profit. Many provider groups are arguing that their reimbursement rates for the services they provide are too low, and they need the surplus payments to cover extra costs. It is true that reimbursement rates for certain services are too low. This is certainly true for oncology nursing, which I know from personal experience is essential to cancer treatment. In fact, last year I taped a message for a video about the importance of oncology nursing and nurses and the need to improve their rates of reimbursement. But I want to make it clear that just because these rates are too low does not mean it is all right for other rates to become too high.

Congress and the Centers for Medicare and Medicaid Services need to act now to end this practice. We need to make sure that Medicare is neither overpaying nor underpaying for any services. To do otherwise threatens the very stability of Medicare and the ability of our doctors to provide important health care. We must stop the gouging of our seniors and constituents by drug companies looking to gain a little market share.

Mr. Chairman, I am glad you are holding this hearing, and I look forward to working with you in the future.

Mr. GREENWOOD. The Chair thanks the gentlelady and recognizes the gentleman from Georgia Mr. Deal for an opening statement. Mr. Deal's not here.

Dr. Ganske for an opening statement.

Mr. GANSKE. Thank you, Mr. Chairman.

I think it is important to have this hearing. We need to look at the concept of the average wholesale price. In my mind the question is, is it the wrong concept for us to be using in terms of reimbursement, or is the information-gathering and the actual way that it is being implemented wrong, and does that need to be improved?

We have to remember that we are not just talking about Medicare, we are talking about Medicaid and also proposals to provide prescription drug coverage for Medicare recipients. I have a proposal, for instance, that would extend Medicaid coverage to the neediest, and so I think that—and the way the AWP has done is important. We need to address issues of potential fraud.

But I want to say this: This last Sunday I gave a speech at my church on September—about the events on September 11, and it was pretty emotional, but it was especially emotional for me because I sat next to my former district staff director, who has advanced lung cancer and is getting chemotherapy. And I will tell you, Mr. Chairman, it makes me rather angry to hear people sit up here and pontificate about the motives of the physicians who are taking care of Luke. What is medical necessity in his case? Some of the things that I have heard would indicate that we questioned the motives of the doctors who are taking care of him because they can't cure him, but they are giving him chemotherapy that may give him a couple extra months of life. I would ask my colleagues how much is that worth?

So let us get away from some of this rhetoric up here about the motives. Let us talk some of the facts. Here is a fact. When Luke goes in for chemotherapy, his doctor is paid $62 for the administration of that chemotherapy. Just the cost of the nursing help is probably over $100. We are not even talking about if he is a Medicare patient. We are not even talking about the cost of the overhead. It is likely that the cost for that physician to administer that type of chemotherapy for a Medicare patient, reimbursement by Medicare is less than one-half, maybe less than one-fourth of what the actual costs are, and that isn't even taking into consideration the amount of time for the personnel and the physicians involved with the multiple phone calls that chemotherapy patients put in to a physician's office.

So when we're talking about this threat, let us also talk about the threat in Medicare and the totally inadequate payment of Medicare services for this, because this is really important. If this

isn't addressed, then those Medicare patients ultimately will not get the type of care that they need, like my friend needs right now.

So let us look at fixing this AWP. Maybe it can be fixed. Maybe we can prevent some of the problems. But you know what? I'd have to say this. If a Medicare HMO negotiates a discount with a pharmaceutical company and thereby increases its profits, is that fraud? Should we be looking at that?

My suggestion is this: Why don't we get the actual data on the average wholesale price. Let us collect the slips and find out what the pharmaceuticals are actually charging and being paid. I would predict then that you will see, when you get a more accurate AWP, you'll see some changes in that, in those amounts, and you'll then get a more accurate index of what, for instance, the reimbursement truly ought to be for the physician services.

So, Mr. Chairman, I think it's a pretty important hearing, and I would just ask my colleagues to look at this in a rational way. Thank you.

Mr. GREENWOOD. The Chair thanks the gentleman and assures the gentleman that it is our intention to make sure that oncologists and all providers are adequately compensated—appropriately compensated, and, in fact, it will be the testimony of the General Accounting Office that will give us the facts that we need to determine what that reimbursement should be.

The Chair recognizes for an opening statement the gentleman from Texas Mr. Hall.

Mr. HALL. Mr. Chairman, thank you, and I think Mrs. Capps really hit the nail on the hit when she talked about priorities, because we all have priorities, and I think it is great of this chairman and the ranking member to hold this hearing in the midst of all the anxieties that the people have all across this country.

This is very important, and I suppose if I could say anything to add to the opening statements that's been made, it would be that I'd like to see us come together, not slapping one another around, but to come together to solve these problems, Medicare, Medicaid, Social Security, the needs that the people have out there, and come together as closely as we're together after the President's speech last night on foreign affairs and offense and defense. That is what is really needed.

I'm very interested in the studies that have been made by GAO and CMS. I hope they're on current data on costs for physicians, particularly in chemotherapy, because in my family I have that problem, have had that problem to one very dear to me. We've all—we are all what our experiences are. But I think the very fact that we have all these empty seats here indicates that we are in a busy time, in an anxious time, and I thank you for having this hearing.

I support the hearing and the things that we're going to have here, and I'd make a request, if it has not already been made, that we be allowed to submit questions and leave them on the record to have their answers put into the record to where the rest of the Congress and the rest of the Nation might have the benefit of this hearing, and I yield back my time.

Mr. GREENWOOD. Without objection, questions posed by members of the committee will be included in the official record.

The Chair now recognizes the gentleman from Pennsylvania Mr. Pitts for his opening statement.

Mr. PITTS. Thank you, Mr. Chairman. I want to commend you and the staff and the whistleblowers for uncovering this serious abuse in the Medicare drug reimbursement system. The system deeply is in need of reform, and I want to thank you for holding this important hearing. I look forward to hearing from your distinguished witnesses today. Thank you. I yield back.

Mr. GREENWOOD. The Chair recognizes the gentleman Mr. Stupak for an opening statement.

Mr. STUPAK. Thank you, Mr. Chairman. I'll waive my opening statement. Just thanks for having this hearing. I look forward to the testimony we're going to hear today.

Mr. GREENWOOD. The Chair recognizes for an opening statement the gentleman from Georgia Mr. Norwood.

Mr. NORWOOD. Thank you, Mr. Chairman.

I wonder if I could identify who developed that slide while I'm beginning my opening statement so we can know who to talk to about it and try to understand it. But I do thank you for holding this important hearing this morning, and in the interest of time, I'm going to try to be brief.

It is clearly obvious that CMS needs to be in a responsible way paying for drug therapies that it does cover under Medicare, and if CMS is overpaying, then that problem needs to be corrected, period, now. If there is fraud in any way occurring with the AWP, that problem needs to be corrected now.

But the tone of the hearing is one in which I think we ought to be a little concerned about, and I'll spend my time talking about that. If our effort here is to try to find somebody to blame or scapegoats, we need to look, I believe, at other obvious points and the bigger picture that might be leading to some of these type of things.

I don't think it's a joke or anybody misunderstands that Medicare significantly underpays providers for many services, and you may not believe me or Dr. Ganske or Dr. Coburn or others who have been saying for years that is the case, and it is getting worse and worse, but it is the case, whether you believe us or not.

I don't think we need to pat ourselves on the back today and think we're making real progress on this one particular problem through this hearing, because the truth of the matter is we are still ignoring the fundamental problem of Medicare. Health care costs money, folks, and it is hard to understand sometimes why—when a patient is dying, perhaps the oncologist is continuing to inject that patient to buy them a few more months or weeks or make their life a little bit better.

Now, maybe we don't want to pay for that. Maybe we want to say that we don't want to pay for that, but let us be honest with our constituents. Let us be honest as a government entity. If we don't want to pay for that or can't, for pity sakes, stand up and say so. Don't try to find a scapegoat to blame.

Now, I don't understand the slide in the back of the room. I have a hunch the implication there is that, for example, Leucovorin costs $1.25, and isn't it absolutely awful that the provider might be charging $42 to use that injection? How could he possibly charge

so much money when it only costs $1.25? Well, how about extending that slide all the way out over to here and show the real cost rather than to imply that one of our oncologists is just trying to rip you off. That is all it is. The poor government is getting beaten up by the medical profession because they would dare charge $42 for a chemical that costs $1.25. Now, I don't know if $1.25 is the right cost or not, but I do absolutely know that slide is fraudulent. It is set up there to imply that somebody is ripping somebody off. Yet it ignores all the other costs that Dr. Ganske started to begin to talk about that is inherent in the price of giving that injection.

Now, if our staff is going to present to us information, I would kindly recommend that they present to us factual information and let us get at the truth, not have a witch hunt.

Now, Mr. Scully, you're here. We're going to talk to you about it. If there is fraud going on, get after it. If there are doctors absolutely cheating the system, get after them. But let us be honest about what we are discussing in a government program that year after year after year keeps trying to salvage the problem by paying people less than it costs to deliver services. Maybe we can't change that, but for pity sakes, let us be honest about that with the American people.

I wasn't as brief as I intended, Mr. Chairman. I'm sorry. I yield back the balance of my time.

Mr. GREENWOOD. The Chair thanks the gentleman. We'll deduct that from his round of questioning.

I'll simply indicate to the gentleman that we will recognize that many providers are underpaid. If we can recoup this billion dollars that is being wasted on underpayment for drugs, we'll probably have more than sufficient funds to pay a whole lot of providers.

The Chair recognizes for an opening statement the gentleman from Wisconsin Mr. Barrett.

Mr. BARRETT. Thank you, Mr. Chairman. Thank you for chairing this important meeting.

I agree with the previous speaker that we shouldn't be looking for a scapegoat, but I think at the same time we have a very serious responsibility to make sure that the taxpayers in this country are treated fairly, and according to the information that I have seen in fiscal year 2000, according to the Office of the Inspector General, Medicare could have saved between $887 million and $1.9 billion by paying prices that other government to nongovernment purchasers were paying. These amounts range from 17 to 32 percent to the total $5 billion Part B costs to the government, and the recipients paying the bills.

So we do have an obligation, and we're not just talking about chump change here. This is a large amount of money, and it is our responsibility, I believe, to hold hearings like this to find out exactly what the problem is. So I, again, applaud you, Mr. Chairman, for holding the hearing.

On another note, I know Mr. Scully will be testifying, and I just want to highlight an issue that I think that we also have to address, which is not 100 percent on point, but there is a Federal barrier right now which prevents safety net hospitals from negotiating better prices on in-patient pharmaceuticals. There is an unreasonably narrow interpretation by CMS of a Medicaid provision passed

by Congress to facilitate free market negotiations between drug manufacturers and safety net providers. We need to make it possible for safety net providers to negotiate better prices on in-patient and out-patient drugs, and I hope to explore that further, and I would yield back the balance of my time.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for his opening statement the gentleman from Michigan Mr. Upton.

Mr. UPTON. Thank you, Mr. Chairman, and at the same time, I, too, will ask unanimous consent to put my entire statement into the record.

I just would like to add, we do need reform in the system. It appears to be broken in lots of different ways. We need to help both the beneficiaries as well as the taxpayers. We need to make sure that the providers are adequately compensated in a fair way to make their expenses as well.

We have a good task ahead of us. I welcome the hearing on the debate this morning, this afternoon, and yield back.

[The prepared statement of Hon. Fred Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. Chairman, thank you for calling today's hearing on Medicare's system for reimbursing prescription drugs administered in physicians' offices and certain other settings. As the title of the hearing indicates, the current system serves neither Medicare patients nor the taxpayers well.

What our committee investigators and the GAO have uncovered is not pretty and reflects badly on everyone involved. Medicare's reimbursement system is being used as a tool in the intense competition for drug market share, leading drug manufacturers to overstate—sometimes grossly overstate—the average wholesale prices for their drugs. The often substantial differences between what Medicare will pay for drugs and what the drugs actually cost physicians may be influencing prescribing practices. And Medicare patients—already grappling with the ravages of cancer or other terrible diseases are having their pockets picked—paying twenty percent of sometimes grossly inflated Medicare prices rather than the often much lower actual cost of the drug the doctors are using to treat them. Then they pay again when Medicare premiums rise in response to rising program costs. And the taxpayers, who foot 75 percent of the program's costs, are having their pockets picked as well.

Mr. Chairman, I think all of us will agree today that we need to act quickly to fix the system in the interests of both Medicare beneficiaries and taxpayers.

I hope that today's hearing will give us the information we need to do it right—and the impetus we need to do it quickly. We need to figure out a way to get real data on real acquisition costs so Medicare payments can be adjusted to reflect reality. At the same time, to ensure continued access to care in community-based settings, we need to fix portions of the physician fee schedule to ensure that the true costs of administering these drugs are reimbursed. In short, we need to give CMS the tools it needs, legislatively and administratively, to do its job right and to protect some of the sickest and most vulnerable of Medicare patients.

Mr. GREENWOOD. The Chair thanks the gentleman and turns for an opening statement to the gentleman from Indiana Mr. Buyer.

Mr. BUYER. Thank you for the hearing, and I ask unanimous consent that my statement be placed in the record, and I would also be hopeful—I'm most hopeful that we will not try to demonize those who are dedicated to saving life, whether it be our health care providers or the those of whom manufacture these great drugs that help extend life. I yield back my time.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for an opening statement the gentleman Mr. Bass from New Hampshire.

Mr. BASS. Thank you, Mr. Chairman.

It is clear this is not a simple problem. It will not demand a simple conclusion. I appreciate the two subcommittee chairmen holding this very important hearing, and I'll yield back.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for an opening statement the gentleman from Texas Mr. Barton.

Mr. BARTON. Thank you, Mr. Chairman, and Chairman, both of you, for holding this joint hearing. Let the record show they come to hearings other than energy hearings, that I'm on this subcommittee.

I was visited yesterday in my office by a pharmaceutical chemotherapy company located in my district. They had done some mathematical analysis, financial analysis, not as extensive as what our subcommittees have done, and showed that just based on their review, there was almost a billion dollars that could be saved in the numbers that they looked at and the drugs that they were prescribing, that others were. So I'm going to have to be convinced that the current system is worth saving before I agree to save it.

If I had to vote today, I would vote to say that physicians could not prescribe and treat cancer patients. They can choose one or the other, but they can't do both, because it seems to me that the system that we have today is broken. We can't fix it. So we need to change it. So I'm going to lock forward to the testimony, but put me down as a Doubting Thomas that the current system is worth saving. And with that I yield back the balance of my time.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes for his opening statement the gentleman from Oklahoma Mr. Largent.

Mr. LARGENT. Mr. Chairman, in the interest of time, I want to submit my full statement for the record, and I'll yield back my time.

Mr. GREENWOOD. The Chair thanks the gentleman.

Mr. GREENWOOD. The gentleman from North Carolina for an opening statement, Mr. Burr.

Mr. BURR. Mr. Chairman, let me thank you for this hearing.

Mr. Chairman, every time we look at health care, we find a more difficult animal than sometimes on the surface we think it is. I think what we're looking at today is, in fact, very complicated. I think the important thing for Members to remember is that over the years it has been, in fact, this body that legislates much of what we do in health care. We respond to providers, we respond to patients, and hopefully sometimes we respond to need, the needs that exist in the delivery systems that we have some jurisdiction on.

We seldom get it exactly right. Most of the time we do get some things wrong, and, yes, in the last 7 years with the leadership changes, we have gotten some things wrong. But one thing that I have learned as a member of this committee as we talk about health care policy is that, one, we always have to strive to do a little bit better; and, two, we also have to be very cautious as we make change that we don't make things worse, that we look outside of the area that is our focus to make sure that changes that

we make don't adversely affect other areas of the health care delivery system.

I believe that we'll hear a lot of information today. I as one will take that information and try to put it through that test of how do we make it a little bit better. How do we make sure that we don't adversely affect other areas by not just the actions of this committee potentially in the future, but by some of the questions and some of the documents that, in fact, we put on the record, because I think, as we all know, throughout the health care system, whether you're in a hospital or whether you're in a provider's office today, your legal counsel watches what Congress says and what we do and eventually what we pass. And all of it to some degree is interpreted the same way when lawyers look at liability, and my hope is that Members will remember that as they ask questions, that they make sure that they clarify everything, and that in the end we do something that addresses exactly the problem that we're trying to get to, a faulty average wholesale price for pharmaceuticals in this country. If there are other areas we need to address, I note that this committee will have the will and the patience to do it.

Mr. Chairman, thank you for your time, and I yield back.

Mr. GREENWOOD. The Chair thanks the gentleman.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. ROBERT L. EHRLICH, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MARYLAND

Mr. Chairman, thank you for holding this important hearing on legislative measures to address the Medicare reimbursement for pharmaceuticals. As you know, Medicare drug reimbursement levels affect millions of Americans who face a variety of serious illnesses.

As we will hear today from the GAO testimony and others, our already-strapped Medicare program, which pays for a limited number of critical drug therapies, overpays for the costs of these drugs. For instance, the Committee notes that 24 highly used drugs may be resulting in a Medicare overpayment of at least $750 million annually. I am eager to hear the testimony before us today to learn more about this overpayment and consider ways to save the Medicare program—and Medicare beneficiaries who pay co-payments on these inflated values—a considerable amount of money.

While it is crucial to address the overpayment calculation for these drugs, I also see the other side of the argument. As I learned during the August District Work Period, providers of care depend upon these overpayments to provide critical care to their patients. As we will also hear today, Oncology treatment facilities represent the front line of defense for nearly 80% of cancer patients in our country.

Many in the cancer community acknowledge that the Medicare program employs a flawed reimbursement structure which *overpays* them for drugs. At the same time, however, they argue that Medicare also *underpays* for many services. For example, Medicare does not adequately support the critical role played by oncology nurses in the care of seniors and people with disabilities. In visiting an Oncology treatment facility in my district recently, I saw first-hand that preserving patient access to cancer care may only be achieved by simultaneously fixing Medicare's flawed reimbursement of cancer drugs and cancer services. Such serious flaws have forced these caregivers to engage in a form of "cost shifting" in which they use drug overpayments to offset Medicare's underpayment for the treatment services provided to beneficiaries. This is source of great uncertainty for seniors with cancer and places significant pressures on the professional caregivers who treat them. Given these two sides of the argument—with patients in the middle simply seeking quality care—I am eager to review the testimony of our witnesses and hope that we move forward to reform Medicare appropriately with the best interests of patients in mind. Mr. Chairman, I realize your deep concern about these issues as well and thank you for your leadership. I look forward to our witnesses' testimony and to working with you and our colleagues to ensure patient access to high quality care.

PREPARED STATEMENT OF HON. ELIOT ENGEL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. Chairman, let me first express my profound sadness over the events of last week and extend my sincerest sympathy to the families of all the victims. But we must continue the business of the people. Today's hearing is focusing on how Medicare reimburses for drugs. It is apparent that it is a complex problem that affects many different areas, from patients, to physicians, to drug companies. Any proposed fix must consider the ramifications for all of these groups, however, the interests of Medicare recipients must be our top priority.

Congress must consider any proposed fix carefully. There have been several attempts to address this issue, which have either failed to become law or failed when they became law and were repealed. The goal that we must keep in mind here is that seniors receive safe, effective, low-cost care. In order to achieve that end, providers must be adequately reimbursed for drugs and the services they provide but fraud and abuse must be rooted out. In the past, Congress has fallen back on AWP (average wholesale price) when providers have said that they were not being reimbursed for their costs. Instead of considering new reimbursement policies, AWP was used to cover these costs. Now, this money may be taken away and providers will be left with inadequate reimbursements for their services. Clearly we must be sure to consider these circumstances.

There is no doubt that there is fraud and abuse because of AWP. I think we do need to fix this problem, but we need to make it better, not worse. I have introduced legislation to address one of the major problems with home infusion therapy. My bill, HR 2750, the Medicare Home Infusion Therapy Act, addresses the particular problems associated with home infusion therapy. Medicare's reimbursement policy for home infusion therapy is simply outdated. Modern medicine has made the administration of many drugs safe and effective in the home. However, because of ludicrous reimbursement provisions seniors are forced to stay in hospitals or trek to physicians offices on a daily basis to receive their treatment. In many cases, this treatment can be conducted in the home safely and at a fraction of the cost. To address this issue, HR 2750 directs the Secretary of Health and Human Services to set up a fee schedule for drug reimbursements and provider reimbursements that would ensure adequate and fair payments to providers. I feel that this legislation appropriately addresses the needs of seniors and providers and could serve as a model for a broader approach to the problems with AWP. I urge this Committee to examine this legislation closely and I also ask you, Mr. Scully, to work with me on this issue.

I want to thank all of our witnesses for attending this hearing today under such difficult circumstances. I look forward to hearing your testimony.

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Thank you Mr. Chairman for holding this hearing on Medicare's reimbursement system for oncology treatments.

In light of last week's events, it is difficult to get too worked up about issues like Medicare reimbursements and practice expenses.

But the truth is that we must continue to do our job in Washington, and as members of this committee, we must continue to improve our Medicare system for beneficiaries and providers.

This issue is an important one. Each day, 3,400 Americans learn that they have cancer. Every minute, another American dies from some form of this disease.

Cancer costs our country more than $107 billion each year.

And with more than 60 percent of all cancers being diagnosed in individuals over age 55, the Medicare programs is bearing a significant burden for treating cancer patients.

When the Medicare reimbursement system was first developed, most cancer patients went to the hospital to receive treatment.

But nowadays, eighty-five percent of these cancer patients are receiving their treatment at out-patient cancer centers.

Our reimbursement system does not reflect the changing world of cancer treatment.

Medicare's reimbursement system for cancer drugs is based on an artificial average wholesale price or (AWP).

As our witnesses will testify, however, this AWP is dramatically inflated for cancer drugs, causing the Medicare program and its beneficiaries to pay exorbitant costs for their life-saving cancer therapies.

Medicare reimburses for 95% of the AWP for oncology drugs.

But, because the AWP does not actually reflect the costs of oncology drugs, physicians are being reimbursed for considerably more than they are paying.

As a result, physicians could be prescribing drugs based on how much they'll profit from them.

There are allegations that physicians won't prescribe a newer, more effective drug, because they don't profit enough.

Now oncologists, like most other Medicare providers, are underpaid for their practice expenses.

As the GAO will testify, oncologists are underpaid by as much as 15%. They use the windfall from the AWP to make up for the underpayment from practice expense.

This system is bad for patients, is wasteful, and is poor public policy.

There is no question on either side of this debate that the current system is broken.

But we must be careful to repair it in a way that does not endanger cancer patients.

We were all troubled by recent media reports where a pharmacist in Kansas was adulterating chemotherapy drugs, reducing their potency, and endangering the lives of cancer patients.

We must ensure the integrity and quality of our cancer treatment system.

But the reimbursement system we have in place must be changed.

It encourages dishonest behavior by both the pharmaceutical manufacturers and the oncologists.

It results in higher costs for both the program and the beneficiaries—patients who are probably facing the most daunting health crisis of their lives.

But whatever solution we craft over the coming months, we must ensure that all Medicare beneficiaries have access to the life saving cancer therapies that they need.

I look forward to the testimony of our witnesses, and I yield back the balance of my time.

PREPARED STATEMENT OF HON. BOBBY L. RUSH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. Chairmen, I want to express my thanks to both of the Chairmen for holding this very important joint hearing on the reimbursement system for prescription drugs under the Medicare Part B program. While the Part B prescription drug program is a relatively small component of universe of prescription drugs used by seniors and others, it is, nonetheless, of critical importance to its users.

The Part B program covers those drugs used with durable medical equipment (DME) or infusion devices, and the host of drugs administered in the treatment of cancer, hemophilia, organ transplantation, emphysema, asthma, kidney dialysis, AIDS, and pain management therapies which are administered on an out-patient basis or in home settings. Many Medicare beneficiaries rely on these life-giving medications and we must ensure their availability and affordability.

Since the beginning of the Medicare Part B program for drug reimbursements, the cost of medications for beneficiaries under this program has grown significantly. Current estimates are that the cost of drug reimbursements has doubled in the last five years.

I am particularly concerned about the special needs of some of the users of these drugs, and have a number of questions about the coverage provided. For example, in hemophiliacs, what is the difference in cost between home infusion and hospital treatment for a bleeding incident?

I look forward to hearing the testimony of the distinguished panel of witnesses and to getting the answers to these, and many other questions regarding the reimbursement rates and processes under Medicare Part B program.

Thank you.

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Chairman Greenwood and Chairman Bilirakis, thank you for convening this hearing on Medicare's payment policy for prescription drugs. I realize that this hearing may not seem terribly important in light of the tragedy that struck our Nation on September 11th. The victims of these horrific attacks, their families, friends, and coworkers, and the security and safety of the American people are all at the forefront of our minds.

Yet in a time when government resources may be needed for purposes none of us could have imagined two weeks ago, we have an added responsibility to ensure that more routine government expenditures are not wasteful. This hearing concerns improper and excessive payments on behalf of the Medicare program. As stewards of Medicare, the Committee cannot and should not allow this practice of overpayments for prescription drugs to continue.

However, before we rush to fix the problem with legislation, we must ensure that any solution will do nothing to harm the patients who need these drugs. We must also be conscious of the impact any change we consider would have on the overall Medicare reimbursement system and other health care payers.

Medicare pays for prescription drugs on an outpatient basis in limited circumstances. One of these circumstances occurs when drugs are administered by a physician, oftentimes during the treatment of cancer. Medicare's reimbursement formula is set at 95 percent of the drug's average wholesale price, or "AWP." The problem with this formula is that AWP is an artificial number reported by the drug manufacturer. In fact, some drug manufacturers deliberately inflate the AWP that they report in order to make the drug more attractive to physicians. The results of this dubious behavior are higher copayments for seniors, an incentive for patients to receive wrong or unnecessary drugs, and waste to the Medicare program.

Congress has been aware of the problem with the current formula for many years. Today, however, the stakes are higher, because any solution we create could have a far-reaching effect on the senior citizens of this country. This Committee will be considering a broad prescription drug benefit in Medicare. It is crucial that the Committee focus on developing a new reimbursement formula that is accurate and workable, based upon a benchmark price that cannot be manipulated.

At today's hearing, some groups will testify that these outrageous overpayments for prescription drugs are necessary to make up for Medicare's under-payments for administering them. In correcting the drug reimbursement formula, the Committee should carefully examine this issue. We certainly do not want to create a situation where patients who need these drugs cannot find the drugs or a physician to administer them.

However, the primary issue before us today is that of prescription drug pricing. Billions of dollars have already been wasted—dollars that could have been spent providing broader prescription drug coverage to seniors. We have a duty to make sure that this practice stops, and to concentrate on creating a Medicare drug benefit where seniors are protected from price-gouging incentives.

Mr. GREENWOOD. The Chair now calls forward our first panel: Mr. William J. Scanlon, the Director of Health Care Issues for the General Accounting Office; the honorable George Grob, Deputy Inspector General, Department of Health and Human Services; and Mr. Zachary Bentley, the President of Ven-A-Care, Inc.

Thank you, gentlemen, for your presence today. This is a joint hearing between the Energy and Commerce Subcommittee on Oversight and Investigations as well as the Subcommittee on Health. The Oversight and Investigation Subcommittee is an investigative subcommittee, and as such we've had the practice of taking testimony under oath. Do any of you object to testifying under oath?

Seeing no such objection, the Chair then advises each of you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do any of you desire to be advised by counsel during your testimony today?

Seeing no such request, in that case, would you please rise and raise your right hand, and I will swear you in.

[Witnesses sworn.]

Mr. GREENWOOD. Thank you. You are now under oath, and we will recognize first Mr. Scanlon for his 5-minute opening statement. Welcome, sir.

TESTIMONY OF WILLIAM J. SCANLON, DIRECTOR, HEALTH CARE ISSUES, GENERAL ACCOUNTING OFFICE; GEORGE F. GROB, DEPUTY INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND ZACHARY T. BENTLEY, PRESIDENT, VEN-A-CARE, INC.

Thank you very much, Mr. Chairman, and members of the subcommittees. I'm pleased to be here today to discuss this important issue and wish to share with you some of the work that we've been doing on the payment by Medicare for prescription drug coverage—the prescription drugs that it covers. We are releasing today a study that was requested in the Beneficiary Improvements and Protection Act on Medicare's pricing of these drugs and will soon release a related study on payments for drug administration services under Medicare's physician fee schedule.

Today I'd like to provide highlights of these two studies, both of which underscore the need for payment method modifications. Our drug pricing study's findings echo those of the Inspector General, the Justice Department, CMS and this committee's. All reveal that Medicare's method, as we've heard, for establishing drug payments is flawed. Simply put, tying Medicare's drug payment to AWP is a recipe for inflation and excess payments.

Even though AWP is often labeled a retail or sticker price, it's not even that. A price is what a purchaser pays for a product. AWP is closer to just a number that manufacturers can specify without rules or criteria, a number not constrained by the need to have a purchaser willing to pay it.

Like the Inspector General, we found that in 2001, wholesalers' catalog prices that would be available to any physician or pharmacy or supplier involved sizable discounts from the AWP. These conservative estimates of providers' acquisition costs indicated that discounts on physician-billed drugs, mostly chemotherapy drugs, ranged from 13 to 34 percent on most drugs and in some cases were even higher. Discounts on two inhalation therapy drugs that account for three-quarters of all the drugs billed to Medicare are startling: 78 percent for one and 85 percent off of AWP for the other.

Medicare's troubling experience in terms of drug pricing is often contrasted with that of the Veterans Administration. As the VA is essentially a health care provider and not a third-party payer like Medicare, its approach cannot simply be transferred to the Medicare program, but key elements can be emulated.

The VA uses the leverage of its and other Federal purchasers' volume to secure prices that are similar to those of other volume purchasers' market prices that someone actually pays. To accomplish this, it uses its leverage to get verifiable data on actual market transactions to establish price schedules. Furthermore, for selected drugs, it has consolidated purchasing power even more and used competition to secure even lower prices.

CMS is in a similar position in that it has available to it comparable information on market prices through the Medicare drug rebate program. We are recommending that CMS assess how it can use those data to ensure that Medicare's payments more closely reflect market prices and to explore how competitive procurements might be effectively used.

Let me turn now to the issue of payments for drug administration. As has been indicated clearly, there is widespread agreement in terms of drug pricing. Our findings are not controversial. However, providers have indicated that underpayment in terms of drug administration needs to be made up for by overpayments in the drug purchase area.

Our second report looks at payments for drug administration under the physician fee schedule, which include the bulk of chemotherapy administration services provided by oncologists.

In the past, we have examined the then-named HCFA's development of the resource-based practice expense component of physicians' fees. That is the part of physician fees meant to reflect the cost of operating a practice, like nursing and administrative staff, equipment, rent and utilities. We concluded then that the Agency's basic method of computing these fees was sound. It achieves the goal laid out by the Congress; that is, to stop having the money Medicare pays physicians distributed according to what physicians historically charge for their services, and to have that money distributed according to the relative amounts of resources needed to provide each service.

The implementation of the revised fee schedule, though, has been controversial. Since Medicare payments in the aggregate were deemed adequate, the Congress required that the new fees be budget-neutral. Then if one specialty's fees increased on average, some others would have to decline. Such redistributions have occurred, and some are quite significant. Oncology is one of the specialties that gain under the new fee schedule. Its practice expense payments are 8 percent higher than they would have been if the prior method of setting fees stayed in place. However, that does not mean that we do not believe there is a problem in the way fees for services, like chemotherapy administration by nurses, are calculated.

HCFA modified its basic method in computing payments for services delivered without direct physician involvement, which include chemotherapy administration as well as some services provided by other specialties. The modifications were intended to correct for perceived low payments for these services, and while they did increase payments for some, they lowered them for many others. Moreover, the modifications increased payments on average for services that did involve physicians directly. Oncology payments were more affected by these modifications, because their services not involving direct physician participation constitute a bigger share of their billings than other services. These services for oncologists are about one-third of their billings compared to 5 percent for all physicians.

The payments for nonphysician chemotherapy administration are on average 15 percent lower than if HCFA used this basic method. On the other hand, practice expense payments for services provided by oncologists themselves are 1 percent higher because of these changes. Using the basic method, which we believe is correct, for all services would increase practice expense payments to oncologists by 6 percent.

We don't think that the HCFA's adjustments, as I've indicated, were appropriate, and our study will recommend that they use the

basic methodology—that CMS use the basic methodology to determine practice expense payments for all services.

Oncologists have raised other concerns about the physician fee schedule, including the representativeness of data used to estimate these practice expenses and whether the data reflects current practices in delivering services.

We are currently conducting another study to determine how CMS can improve and update the information used to estimate practice expenses; however, what impact improved data may have on payments is uncertain. Payments are based on the differences in expenses of one specialty compared to another. Some of the data concerns raised by oncologists may apply equally well to other specialties so that additional and many current data may reveal that the relative cost of different specialty services would only change modestly.

Overall, let me say in conclusion, we believe that it should be a principle of Medicare payment policy to pay for each service appropriately and not to rely on overpayments for some to offset inadequate payments for others. An efficiently operated Medicare program needs payments that reflect market prices so that it benefits from the discipline imposed by other payers. It also needs to judiciously use the buying power associated with its size to secure even greater efficiencies, though that must be balanced with its responsibilities to assure access for beneficiaries and to treat providers fairly.

Thank you very much, Mr. Chairman. I'll answer any questions you have.

[The prepared statement of William J. Scanlon follows:]

PREPARED STATEMENT OF WILLIAM J. SCANLON, DIRECTOR, HEALTH CARE ISSUES, UNITED STATES GENERAL ACCOUNTING OFFICE

Messrs. Chairmen and Members of the Subcommittees: I am pleased to be here as you discuss the pricing of Medicare's part B-covered prescription drugs. The pricing of these drugs—largely drugs that cannot be administered by patients themselves—has been under scrutiny for several years. Most of the part B drugs with the highest Medicare payments and billing volume fall into three categories: those that are billed for by physicians and typically provided in a physician office setting (such as chemotherapy drugs),[1] those that are billed for by pharmacy suppliers and administered through a durable medical equipment (DME) item (such as a respiratory drug given in conjunction with a nebulizer[2]), and those that are also billed by pharmacy suppliers but are patient-administered and covered explicitly by statute.[3] Studies by the Department of Justice, the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG), and the House Committee on Commerce show that Medicare's payment for these drugs in some cases is significantly higher than the actual costs to the physicians and other providers who bill Medicare for these products.

In September 2000, the Health Care Financing Administration (HCFA)—now the Centers for Medicare and Medicaid Services (CMS)[4]—took steps to reduce Medicare's payment for part B-covered drugs by authorizing Medicare carriers, the contractors that pay part B claims, to use prices obtained in the Justice Department investigations of providers' drug acquisition costs. HCFA retracted this authority in November 2000 following concerns raised by providers. In December 2000, as part

[1] In the case of chemotherapy drugs, the common practice is for a nurse to provide the services to administer the drug and for the physician to bill Medicare accordingly.

[2] A nebulizer is a device driven by a compressed air machine. It allows the patient to take medicine in the form of a mist (wet aerosol).

[3] Medicare-covered drugs and biologicals that can be self-administered include such drugs as blood clotting factors and some oral drugs used in association with cancer treatment and immunosuppressive therapy.

[4] Our statement refers to HCFA when discussing actions it took under that name.

of recent Medicare legislation,[5] the Congress asked us to study Medicare's payments for part B-covered drugs and make recommendations for pricing methodology refinements. We have reported our findings and made recommendations, as mandated, today.[6]

My remarks today will focus on (1) Medicare payment policies to cover part B-covered drug costs and costs of administering the drugs and (2) key features of other payers' reimbursement policies that suggest opportunities to improve the appropriateness of Medicare's payments. My comments are based primarily on our study of Medicare payments for part B-covered drugs and a forthcoming study of physicians' practice expense payments under Medicare's fee schedule.

In summary, our study shows that Medicare's method for establishing drug payments is flawed. Medicare pays 95 percent of the average wholesale price (AWP), which, despite its name, may be neither an average nor what wholesalers charge. It is a price that manufacturers derive using their own criteria; there are no requirements or conventions that AWP reflect the price of any actual sale of drugs by a manufacturer. Manufacturers report AWPs to organizations that publish them in drug price compendia, and Medicare carriers that pay claims for part B drugs base providers' payments on the published AWPs.

We found that, in 2001, widely available prices at which providers could purchase drugs were substantially below AWP, on which Medicare payments are based. For both physician-billed drugs and pharmacy supplier-billed drugs, Medicare payments often far exceeded widely available prices. Despite concerns about what discounts may be available to smaller-volume purchasers, physicians who billed Medicare for low volumes of drugs reported receiving discounts from AWP, for most drugs, that were similar to or greater than those afforded by the widely available prices we documented.

Physicians and pharmacy suppliers contend that the excess payments for covered drugs are necessary to offset what they claim to be inappropriately low or no Medicare payments for services related to the administration or delivery of these drugs. For administering physician-billed drugs, Medicare makes explicit payments under the physician fee schedule. Our forthcoming review of practice expense payments under the fee schedule will make several points regarding oncologists' payments. It will show that Medicare's payments to these specialists were 8 percent higher than they would have been if the program's prior payment method had remained in place and will show that oncologists' payments relative to their estimated practice expenses were close to the average for all specialists. However, we will also show that HCFA made questionable modifications to its basic method of setting practice expense payments, which resulted in lowering the average fees paid for the administration of drugs by physicians' staffs.

For delivering pharmacy supplier-billed drugs, Medicare's payment policies are uneven. Pharmacy suppliers billing Medicare receive a dispensing fee for one drug type—inhalation therapy drugs—but there are no similar payments for other DME-administered or oral drugs. However, Medicare pays DME suppliers for the rental or purchase of equipment and supplies, and long-standing problems in the program's payments for these items may result in overpayments that implicitly compensate for some service delivery costs not covered.

Other payers and purchasers, such as health plans and the Department of Veterans Affairs (VA), employ different approaches in paying for or purchasing drugs that may be instructive for Medicare. In general, they make use of the leverage from their volume and competition to secure better prices. The federal purchasers, furthermore, use that leverage to secure verifiable data on actual market transactions to establish their price schedules. Private payers' practices—such as negotiating prices that result in selecting certain products or suppliers and arriving at terms without open competition—would not be easily adaptable to Medicare, given the program's size and need to ensure access for providers and beneficiaries. How other federal agencies have exercised their leverage may offer more applicable lessons.

BACKGROUND

The traditional Medicare program does not have a comprehensive outpatient prescription drug benefit, but under part B (which covers physician and other outpatient services), it covers roughly 450 pharmaceutical products and biologicals.[7] In

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[5] The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (P.L. 106-554, Appendix F).

[6] *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs* (GAO-01-1118, Sept. 21, 2001.)

[7] For the remainder of this statement, we will refer to "drugs and biologicals" as "drugs."

1999, spending for Medicare part B-covered prescription drugs totaled almost $4 billion.[8]

Small Number of Products Accounts for Largest Shares of Program Spending and Claims Volume

A small number of products accounts for the majority of Medicare spending and billing volume for part B drugs. In 1999, 35 drugs accounted for 82 percent of Medicare spending and 95 percent of the claims volume for these products.[9] The 35 products included, among others, injectible drugs to treat cancer, inhalation therapy drugs, and oral immunosuppressive drugs (such as those used to treat organ transplant patients).

The physician-billed drugs accounted for the largest share of program spending, while pharmacy supplier-billed drugs constituted the largest share of the billing volume. Three specialties—hematology oncology, medical oncology, and urology—submitted claims for 80 percent of total physician billings for part B drugs. Two inhalation therapy drugs accounted for 88 percent of the Medicare billing volume for pharmacy-supplied drugs administered in a patient's residence.[10]

Medicare Payments for Drugs Are Based on Published AWPs

Medicare's payment for part B-covered drugs is based on the product's AWP, which is a price assigned by the product's manufacturer and may be neither "average" nor "wholesale." Instead, the AWP is often described as a "list price," "sticker price," or "suggested retail price."

The term AWP is not defined in law or regulation, so the manufacturer is free to set an AWP at any level, regardless of the actual price paid by purchasers. Manufacturers periodically report AWPs to publishers of drug pricing data, such as the Medical Economics Company, Inc., which publishes the Red Book, and First Data Bank, which compiles the National Drug Data File. In paying claims, Medicare carriers use published AWPs to determine Medicare's payment amount, which is 95 percent of AWP.[11] Thus, given the latitude manufacturers have in setting AWP, these payments may be unrelated to market prices that physicians and suppliers actually pay for the products.

Drug Supply Chain Involves Multiple Parties and Arrangements That Influence the Net Price to the End Purchaser

The actual price that providers pay for Medicare part B drugs is often not transparent. Physicians and suppliers may belong to group purchasing organizations (GPO) that pool the purchasing of multiple entities to negotiate prices with wholesalers or manufacturers. GPOs may negotiate different prices for different purchasers, such as physicians, suppliers, or hospitals. In addition, providers can purchase part B-covered drugs from general or specialty pharmaceutical wholesalers or can have direct purchase agreements with manufacturers.

Certain practices involving these various entities can result in prices paid at the time of sale that do not reflect the final net cost to the purchaser. Manufacturers or wholesalers may offer purchasers rebates based on the volume of products purchased not in a single sale but over a period of time. Manufacturers may also establish "chargeback" arrangements for end purchasers, which result in wholesalers' prices overstating what those purchasers pay. Under these arrangements, the purchaser negotiates a price with the manufacturer that is lower than the price the wholesaler charges for the product. The wholesaler provides the product to the purchaser for the lower negotiated price, and the manufacturer then pays the wholesaler the difference between the wholesale price and the negotiated price.

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[8] Spending is defined as Medicare's total payment, of which Medicare's share is 80 percent and the beneficiaries' share is 20 percent.

[9] Our analysis excluded some high-volume and high-expenditure drugs because of inadequate pricing data. Volume for a drug is measured in terms of the number of units provided. Analyses exclude data on services supplied in Puerto Rico and the U.S. Virgin Islands and exclude payments made on behalf of Railroad Retirement Board beneficiaries.

[10] These two drugs are ipratropium bromide and albuterol (unit dose form).

[11] Technically, the payment equals 95 percent of AWP for the drugs grouped under each HCFA Common Procedure Coding System (HCPCS) code. Individual drugs are identified by the National Drug Code (NDC). NDCs are assigned by the Food and Drug Administration and are the universal product identifiers for drugs for human use. Each NDC specifies a chemical entity, manufacturer, dosage form, strength, and package size. For example, a single drug—marketed by one manufacturer in one form and strength but in three package sizes—would have three NDCs. Because one HCPCS code may have multiple NDCs, the carriers determine the Medicare payment by analyzing multiple NDCs' AWPs. For multisource drugs, the payment allowance is 95 percent of the lower of (1) the median AWP of all generic forms of the drug or (2) the lowest brand name product's AWP.

MEDICARE'S PAYMENT FOR PART B-COVERED DRUGS IS SIGNIFICANTLY HIGHER THAN PRICES WIDELY AVAILABLE TO PROVIDERS

For the part B-covered drugs accounting for the bulk of Medicare spending and claims, Medicare payments in 2001 were almost always considerably higher than wholesalers' prices that were widely available to physicians and suppliers. This was true regardless of whether the drugs had competing products or were available from a single manufacturer. Physicians who billed Medicare for relatively small quantities of these drugs also obtained similar prices.

Wide Disparities Exist Between Drug Acquisition Costs and Medicare Payments

Our study shows that there can be wide disparities between a drug's estimated acquisition cost and Medicare's payment for that drug. Physician-billed drugs account for the bulk of Medicare spending on part B drugs. Of those billed by physicians, drugs used to treat cancer accounted for most of Medicare's expenditures. Specifically:

- Widely available discounts for 17 of the physician-billed drugs we examined averaged between 13 percent and 34 percent less than AWP.
- For two other physician-billed drugs, Dolasetron mesylate and Leucovorin calcium, average discounts were considerably larger—65 percent and 86 percent less than AWP.

The discounts on physician-billed drugs, based on wholesaler and GPO catalogue prices, are notably lower than Medicare's payment, which reflects a discount of 5 percent below AWP. The discounts indicate that Medicare's payments for these drugs were at least $532 million higher than providers' acquisition costs in 2000. Further, the discounts we report may only be the starting point for additional discounts provided to certain purchasers, as chargebacks, rebates, and other discounts may drive down the final sale price.

Concerns have been expressed that small providers either could not or do not obtain such favorable prices. Therefore, we surveyed a sample of physicians who billed Medicare for low volumes of chemotherapy drugs to see if they were able to obtain similar discounts.[12] All of the low-volume purchasers who responded to our survey reported obtaining similar or better discounts than the widely available prices we had documented. More than one-third of these physicians reported belonging to GPOs and obtained the GPOs' substantial discounts, while others said they had contracts with manufacturers and wholesalers.

As with physician-billed drugs, Medicare's payments for pharmacy supplier-billed drugs generally far exceeded the prices available to these suppliers. For the drugs we examined, Medicare's payments were at least $483 million more than what the suppliers paid in 2000. Further, the discounts we report were largest for products that could be obtained from more than one source. Inhalation therapy drugs administered through DME and oral immunosuppressive drugs represent most of the high-expenditure, high-volume drugs billed to Medicare by suppliers. Specifically:

- Two drugs, albuterol and ipratropium bromide, used with DME for respiratory conditions, account for most of the pharmacy-supplied drugs paid for by Medicare. In 2001, they were available to pharmacy suppliers at prices that averaged, respectively, 85 percent and 78 percent less than AWP.
- Other high-volume DME-administered drugs had prices averaging 69 percent and 72 percent less than AWP. These findings are consistent with prior studies of the prices of similar drugs.[13]
- Two of the four high-volume oral immunosuppressives were available from wholesalers with average discounts of 14 percent and 77 percent. Wholesale price information on the other two was not available, but retail prices from online pharmacies were as much as 13 percent and 8 percent below AWP.

Policies to Pay for Related Delivery and Administration Services Vary by Provider

Medicare payment policies for administering or delivering a drug vary, depending on who provides the drug to the patient. Physicians are compensated directly for drug administration through the physician fee schedule. Pharmacy suppliers are compensated for dispensing inhalation therapy drugs used with a nebulizer, which make up the majority of their part B drug claims. No explicit payments are made to pharmacy suppliers for dispensing other drugs, but they may receive payments for equipment and supplies associated with DME-administered drugs. Both physi-

[12] We conducted a telephone survey of a sample of physicians who billed Medicare for a low-volume of cancer treatment drugs in 1999. For more detail, see GAO-01-1118.

[13] Medicare Reimbursement of Albuterol (HHS OIG, OEI-03-00-00311, June 2000) and Medicare Reimbursement of Prescription Drugs (HHS OIG, OEI-03-00-00310, Jan. 2001).

cians and pharmacy suppliers contend that the excess in Medicare's payments for part B-covered drugs compensates for related service costs inadequately reimbursed or not explicitly covered at all.

In prior work on the Medicare physician fee schedule, we concluded that the agency's basic method of computing practice expense payments to physicians was sound.[14] The implementation of this fee schedule, however, has been controversial. The Congress required that payments be budget neutral relative to prior spending. Medicare's physician payments were, in the aggregate, seemingly adequate, as most physicians were participating in Medicare and accepting the program's fees as payment in full. Because of the budget neutrality requirement, if one specialty's fees increased on average, some others would have to decline. Such redistributions have occurred and some are significant.

Oncologists, who represent the majority of physicians billing for drugs, argue that Medicare's payments for administering chemotherapy are inappropriately low and that the excess Medicare drug payments are needed to offset their losses. Yet oncology is one of the specialties to gain under the resource-based physician fee schedule. In our separate study on physicians' practice expenses under Medicare's fee schedule, we will show that payments to oncologists were 8 percent higher than they would have been if the prior charge-based payment method had been maintained; the study will also show that oncologists' payments relative to their estimated practice expenses, which include chemotherapy administration, were close to the average for all specialties.

While oncologists do not appear disadvantaged overall under the fee schedule, adjustments HCFA made to the basic method of computing payments reduced fees for some oncologists' services. In those adjustments, HCFA modified the basic method in computing payments for services delivered without direct physician involvement, like much of chemotherapy administration. The modifications were intended to correct for perceived low payments for these services. While they increased payments for some of these services, they lowered them for many others. Moreover, they increased payments on average for services involving physicians. Oncology payments were particularly affected, as services without physician involvement constitute about one-third of oncologists' Medicare-billed services, compared to about 5 percent of all physician-billed services. Because of the modifications to the basic method, oncology practice expense payments for nonphysician chemotherapy administration were on average 15 percent lower, while payments for physician-administered services were 1 percent higher, than if HCFA had used the basic method. Across all services, the modifications resulted in oncology practice expense payments that were 6 percent lower.[15] Using the basic method for all services would eliminate these reductions and add about $31 million to oncology payments. Our study will recommend that CMS revert to the use of the basic methodology to determine practice expense payments for all services.

We will also recommend that CMS address a data adjustment it made that affects oncology payments under the new fee schedule. The agency reduced oncology's reported supply expenses to keep from paying twice for drugs that are reimbursed separately by Medicare. Oncologists acknowledge that the supply expense estimate needed to be reduced, but argue that the reduction was too large. We have recommended that the agency develop the appropriate data to more accurately estimate oncology supply expenses. Substituting a supply expense estimate based on a methodology developed by the American Society of Clinical Oncology would raise practice expense payments an additional $20 million,[16] if done in conjunction with our recommendation to use the basic method to calculate payments for all services.

Oncologists have raised concerns about whether the data used to estimate their practice expenses constituted a representative sample of practices surveyed and whether these data reflect current practices in delivering services. How improvements in the data to estimate practice expenses may affect payment levels is uncertain. Payments are based on the differences in expenses of services of one specialty compared to those of others. Some of the data concerns raised by oncologists may apply to other specialties as well, so that additional and more current data may reveal that the relative cost of one service compared to others may have changed only

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[14] Practice expenses constitute one of three components in Medicare's physician fee schedule. The other two are work and malpractice expenses. For the physician's average fee in 1999, practice expenses accounted for about 42 percent; work, about 55 percent; and malpractice, about 3 percent.

[15] The source for these figures is our analysis of 2001 practice expense fees, based on 1999 Medicare utilization.

[16] The source for these figures is our analysis of 2001 practice expense fees, based on 1999 Medicare utilization.

modestly. We are conducting a separate study to determine how CMS can improve and update the information used to estimate specialties' practice expenses.

Similar to the physicians who bill for part B drugs, pharmacy suppliers and their representatives contend that the margin on the Medicare drug payment is needed to compensate them for costs not covered by Medicare—that is, the clinical, administrative, and other labor costs associated with delivering the drug. These include costs for billing and collection; facility and employee accreditation; licensing and certifications; and providing printed patient education materials. Medicare pays a dispensing fee of $5.00 for inhalation therapy drugs used with a nebulizer, which are the vast majority of the pharmacy-supplied drugs. This fee was instituted in 1994. It is higher than dispensing fees paid by pharmacy benefit managers, which average around $2.00, and is comparable to many state Medicaid programs, which range from $2.00 to over $6.00. For other pharmacy-supplied drugs, Medicare makes no explicit payment for dispensing the drug.

Besides the profits on the DME-related drugs, pharmacy suppliers may receive additional compensation through the payment for DME and related supplies. Our prior work suggests that, for two reasons, Medicare DME and supply payments may exceed market prices.[17] First, because of an imprecise coding system, Medicare carriers cannot determine from the DME claims they process which specific products the program is paying for. Medicare pays one fee for all products classified under a single billing code, regardless of whether their market prices are greatly below or above that fee.[18] Second, DME fees are often out of line with current market prices. Until recently, DME fees had generally been adjusted only for inflation because the process required to change the fees was lengthy and cumbersome. As a result, payment levels may not reflect changes in technology and other factors that could significantly change market prices.

OTHER PURCHASERS' PRACTICES ARE INSTRUCTIVE FOR REFORMING MEDICARE'S METHOD OF PAYING FOR PART B-COVERED DRUGS

Private insurers and federal agencies, such as VA, employ different approaches in paying for or purchasing drugs that may provide useful lessons for Medicare. In general, these payers make use of the leverage of their volume and competition to secure better prices. The federal purchasers, furthermore, use that leverage to secure verifiable data on actual market transactions to establish their price schedules. Private payers can negotiate with some suppliers to the exclusion of others and arrive at terms without clear criteria or a transparent process. This practice would not be easily adaptable to Medicare, given the program's size and need to ensure access for providers and beneficiaries. How other federal agencies have exercised their leverage may be more instructive and readily adaptable for Medicare.

VA and certain other government purchasers buy drugs based on actual prices paid by private purchasers—specifically, on the prices that drug manufacturers charge their "most-favored" private customers.[19] In exchange for being able to sell their drugs to state Medicaid programs, manufacturers agree to offer VA and other government purchasers drugs at favorable prices, known as Federal Supply Schedule (FSS) prices. So that VA can determine the most-favored customer price, manufacturers provide information on price discounts and rebates offered to domestic customers and the terms and conditions involved, such as length of contract periods and ordering and delivery practices.[20] (Manufacturers must also be willing to supply similar information to CMS to support the data on the average manufacturer's price, known as AMP, and best price they report for computing any rebates required by the Medicaid program.)

VA has been successful in using competitive bidding to obtain even more favorable prices for certain drugs. Through these competitive bids, VA has obtained national contracts for selected drugs at prices that are even lower than FSS prices. These

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[17] See *Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies* (GAO/HEHS-98-102, May 12, 1998).

[18] The equipment and supply payment is determined from a DME fee schedule, whose rates are based on a state-specific fee schedule and subject to national minimum and maximum payment limits. Fees are based on average historical supplier charges that are adjusted for inflation over time.

[19] Under federal procurement regulations, the government seeks to obtain the price is intended to equal or better the price that the manufacturer offers its most-favored nonfederal customer under comparable terms and conditions.

[20] Because the terms and conditions of commercial sales vary, there may be legitimate reasons why the government does not always obtain the most-favored customer price. Hence, under the regulations, VA may accept a higher price if it determines that (1) the price offered to the government is fair and reasonable and (2) awarding the contract is otherwise in the best interest of the government.

contracts seek to concentrate the agency's purchase on one drug within therapeutically equivalent categories for the agency's national formulary. In 2000, VA contract prices averaged 33 percent lower than corresponding FSS prices.

Medicare's use of competition has been restricted to several limited-scale demonstration projects authorized by the Balanced Budget Act of 1997. In one of these demonstrations under way in San Antonio, Texas, suppliers bid to provide nebulizer drugs, such as albuterol, to Medicare beneficiaries. While Medicare normally allows any qualified provider to participate in the program, under the demonstration only 11 bidders for nebulizer drugs were selected to participate. In exchange for restricting their choice of providers to the 11 selected, beneficiaries are not liable for any differences between what suppliers charge and what Medicare allows. Preliminary CMS information on the San Antonio competitive bidding demonstration suggests no reported problems with access and a savings of about 26 percent realized for the inhalation drugs.

CONCLUDING OBSERVATIONS

Our study on Medicare payments for part B drugs shows that Medicare pays providers much more for these drugs than necessary, given what the providers likely paid to purchase these drugs from manufacturers, wholesalers, or other suppliers. Unlike the market-based fees paid by VA and other federal agencies, Medicare's fees are based on AWP, which is a manufacturer-reported price that is not based on actual transactions between seller and purchaser. Physicians contend that the profits they receive from Medicare's payments for part B drugs are needed to compensate for inappropriately low Medicare fees for most drug administration services. Similarly, the case argued by some pharmacy suppliers for Medicare's high drug payments is that not all of their costs of providing the drugs are covered.

In our view, it should be a principle of Medicare payment policy to pay for each service appropriately and not to rely on overpayments for some services to offset inadequate payments for complementary services. If Medicare were to follow this principle and lessons from other payers in setting fees for part B drugs, it would use information on actual market prices net of rebates and discounts—similar to information currently available to VA and CMS—to establish Medicare payments. It could also determine market-based fees, where appropriate, through a competitive bidding process. Medicare would pay for administration and delivery of these drugs separately, as it does currently for drugs supplied by physicians and for inhalation therapy drugs. As the way drugs are supplied and administered varies, different methods of determining payments would be necessary. Paying for these services explicitly would enable Medicare to eliminate implicit payments that may have been made through excessive payments for DME and the drugs associated with the DME payment. In our report, we make recommendations reflecting these lessons to revise the program's payment methods.

Messrs. Chairmen, this concludes my statement. I would be happy to answer any questions that you or Subcommittee Members may have.

CONTACT AND ACKNOWLEDGMENTS

For more information regarding this testimony, please contact me at (202) 512-7114 or Laura Dummit at (202) 512-7119. Other contributors to this statement include Carol Carter, Iola D'Souza, Hannah Fein, Kathryn Linehan, and James Mathews.

Mr. GREENWOOD. Thank you, Mr. Scanlon, for your testimony.

And I recognize Mr. Grob, the Deputy Inspector General for Health and Human Services, for your testimony, sir.

TESTIMONY OF GEORGE F. GROB

Mr. GROB. Thank you, Mr. Chairman, for the opportunity to testify here today. Everyone said Medicare pays too much, and listening to all the opening statements, I'm not sure that I have a whole lot to add to the knowledge that has already been presented.

Mr. GREENWOOD. I'm sure you have more credibility than we do.

Mr. GROB. What I'll try to do, perhaps, is to add some additional pieces of information that may help. First of all, with regard to the amount that we pay too much, the number that is being bandied around is about a billion dollars, and I think that is a fair bottom

line. Here is the reason. Our studies have shown, using the catalogs available that we've been able to find for 24 drugs, which represent about $3.7 out of the $5 billion in the year 2000 that Medicare authorized for the payment of these drugs, that we saw a loss of about $880 some-odd million. Of course, if we had looked at all the drugs, that would have been higher and perhaps pressing a billion dollars. So that is a fair benchmark for people to have in their minds.

But we have to remember that these are catalog prices. These are the numbers that are sort of out there. So when the drugs are actually paid for, it is very likely that the prices are even lower than that. We ourselves did not obtain those lower prices. Ours are the more conservative, just catalog price.

Now, we've also looked at the Federal Supply Schedule which is negotiated by the Veterans Administration, and there, of course, we found a $1.9 billion difference in the spread. Now, many people would say that that's unfair because of the special position that the Veterans Administration is in; that you really can't say, well, Medicare ought to be able to get drugs at those prices. That may be true, but here are some things to think about.

First of all, we assume that the drug companies are making a profit on those drugs, so that that represents a price that they are willing to offer to at least some large buyers. And we're not at all certain, since we ourselves did not look at the actual invoices, of what the spreads are that physicians and others—large suppliers—are actually obtaining on their drugs. Perhaps it's an outer limit, but I think it's fair to say that the actual loss to Medicare is probably in the vicinity of $1 to $2 billion, as best we can tell.

Another point that I would make is that we have reviewed these drug prices intensely, starting in the mid-1980's because, of the effects to Medicaid program as well, but we have been looking particularly hard since 1997. And over the last 4 years, we have never found it to be any way other than what has been described at this hearing. Every study that we do finds these same results. But near the end of my testimony, I'm going to reflect that the gap is widening, and the loss is increasing.

We've talked about the system being flawed, and I think most people describe it well. And I do take to heart the admonition not to get to the motives of people. But I just would like to give two insights about this.

If you were to sit down in an office with an individual, a representative of the drug company here and perhaps a physician here, and say, "Listen, I will sell you the drug for $100, but I will tell Medicare that I sell it for $200, you will have $100, and I will have $100. It's not a bad deal." Someone then might comment that a kind of deal has been made, perhaps games are being played to achieve a higher market share by that drug company, presenting its drug in that way. But that would still be true, even if the meeting doesn't occur in the room. This is not too hard to understand. Simply posting of these numbers on a public list is enough to achieve the same effect. So we have to be wary of the effect even if in the studies that I have done we have not reached the motives of the individuals.

There's also something here that I call "upside-down economics." If I were to ask an undergraduate economic student the following question: "Which company would likely achieve the greatest market share? Is it the one with the highest average wholesale price or the one with the lowest?" And the student were to say: "It's the one with the highest." The professors would say; "That is incorrect. Obviously the company whose wholesale price is the lowest would be the one that would expect to sell more of their product." That is the answer the professor would have to give, of course, unless you're talking about Medicare's payment for prescription drugs—in which the whole theory simply reverses.

The physician community has raised its concerns here, and we certainly take that to heart. We fully support a fair reimbursement under the Medicare program.

Perhaps another insight will help here. What I believe is wrong with the current system is that it's behaving this way. If an individual felt that his mortgage payments were too high, he might want to go to the bank and say: "Since you're charging me so much there, could you reduce my automobile payment?" Well, that's not a good way to do banking, but it might not be an unreasonable question.

The problem with the Medicare program is that in an analogous situation, the automobile dealer and the automobile purchaser are telling the bank how much they will pay for the car payment as opposed to the Medicare program, the Secretary, the Department and the Congress deciding what that amount is. And I believe that that's fundamentally what's wrong, even if we do have some compassionate concern for the dollars that the medical profession needs to carry out what it does.

In any event, whatever system that we do use should not be based on a number that is misnamed, misleading, and make believe.

There are a lot of options to handle this problem, and we've listed them extensively in the testimony that we've provided. It's too detailed to discuss here in my short version of my testimony, but we have made ourselves available and will continue to answer as many technical questions as we possibly can.

Let me end now by making one other remark. I think that we have all felt strongly that we have a problem here that needs to be fixed. What I would like to emphasize is that we fix it now. The first really detailed study that we did of the current phenomenon was in 1997 based on 1996 dollars, and here were the facts then: Medicare's authorization for drugs was $2.3 billion that year. We looked at $1.5 billion and found $447 million that was probably wasteful. Four years later, looking at the data from the year 2000, the amount that Medicare authorized for drugs had more than doubled to $5 billion. We looked at $3.7 billion, and even the conservative estimate, the catalog estimate, we found was double what we found in terms of waste—possible waste for the government was $900 million and possibly as much as $1.9 billion. So every day, every month, every period that we don't solve the problem, the problem gets bigger, and the Medicare expenditures rise. Thank you.

[The prepared statement of George F. Grob follows:]

PREPARED STATEMENT OF GEORGE F. GROB, DEPUTY INSPECTOR GENERAL FOR EVALUATION AND INSPECTIONS, OFFICE OF INSPECTOR GENERAL, HHS

Good morning Mr. Chairman. I am George Grob, Deputy Inspector General for Evaluation and Inspections, Department of Health and Human Services. I am here today to discuss Medicare payments for prescription drugs.

Medicare pays too much for prescription drugs—more than most other payers. The method it uses to determine the amount to be paid is flawed. In fact, it makes no sense at all. It allows the price to be set arbitrarily by drug manufacturers, not the marketplace. Their published wholesale prices for many drugs are far above what suppliers and physicians actually pay for them. This allows physicians, for example, to make substantial profits from the drugs they administer during the course of treatment in their offices. For the year 2000 we found that Medicare's authorized payments for 24 leading drugs were $887 million more than actual wholesale prices available to physicians and suppliers and $1.9 billion more than prices available through the Federal Supply Schedule. Until the system is changed, Medicare and its beneficiaries will continue to pay excessive amounts for prescription drugs; and the amount of excessive payments will increase every year.

MEDICARE COVERAGE AND PAYMENTS FOR PRESCRIPTION DRUGS

Medicare's coverage of outpatient drugs is limited primarily to drugs used in dialysis, organ transplantation, and cancer treatment. Medicare also covers certain vaccines and drugs used with durable medical equipment such as infusion pumps and nebulizers. However, Medicare's total payments for prescription drugs have risen steadily over the past decade. In 1992, Medicare paid about $700 million for prescription drugs; by 2000, it paid $5 billion. Between 1999 and 2000 alone, payments increased by $1 billion. This rapid growth illustrates the necessity of ensuring that Medicare pays reasonable prices for the drugs it covers.

Physicians and suppliers purchase these drugs, administer or provide them to Medicare beneficiaries, and then submit a bill to Medicare for reimbursement. In general, Medicare reimburses physicians and suppliers for 95 percent of the average wholesale price (AWP) published by the drug manufacturers. Of this amount, Medicare beneficiaries are responsible for a 20 percent coinsurance payment.

EXCESSIVE PAYMENTS

Over the past 4 years, the Office of Inspector General has produced a number of reports, all of which have reached the conclusion that Medicare and its beneficiaries pay too much for prescription drugs. Although it might be sufficient for me to quote only from our most recent studies, I would like to summarize all of our work here, because it demonstrates the consistency of our findings and the relentless growth of the problem.

A table summarizing the results of our reports is provided on the next page, followed by a more detailed description.

Summary of OIG Medicare Prescription Drug Reports

Year of Report	1997	1998	2000	2000	2000	2001	2001
Drugs Reviewed ...	22 drugs	34 drugs	5 ESRD drugs	Albuterol	24 drugs	Albuterol	24 drugs
Year Reviewed	1996	1997	1998	1999	1999	2000	2000
Medicare Expenditures for Reviewed Drugs ...	$1.5 billion	$2.1 billion	$379 million	$246 million	$3.1 billion	$296 million	$3.7 billion
Excessive Payments Based On:							
VA		$1 billion	$162 million	$209 million	$1.6 billion	$264 million	$1.9 billion
Catalogs	$447 million				$761 million	$245 million	$887 million
Medicaid			$42 million	$120 million	$425 million		
Beneficiary Share of Excessive Payments	$89 million	$200 million	$32 million	$42 million	$320 million	$53 million	$380 million
			$8 million	$24 million	$152 million	$49 million	$177 million
					$85 million		

Drugs in general

In December 1997, we released a report which compared Medicare payments for 22 drugs to actual wholesale prices available to the physician and supplier communities. These 22 drugs accounted for $1.5 billion of the $2.3 billion in Medicare payments for prescription drugs in 1996. The wholesale prices were computed using catalogs from drug wholesalers and group purchasing organizations which sell drugs to physicians and suppliers.

The report found that Medicare allowances for the 22 drugs exceeded wholesale prices by $447 million in 1996. Medicare paid more than the available wholesale price for all 22 drugs under review. For more than one-third of the drugs, Medicare reimbursement amounts were more than double the wholesale prices available to the physician and supplier community.

We followed up this report in November of 1998 by comparing Medicare allowances for prescription drugs to prices available to the Department of Veterans Affairs (VA) and several other Federal agencies through the Federal Supply Schedule (FSS). (The supply schedule provides agencies lie the VA with a simple process for purchasing commonly-used products in various quantities while still obtaining the discounts associated with volume buying. Using competitive procedures, contracts are awarded to companies to provide services and supplies at the FSS prices over a given period of time.) This report included 34 drugs which accounted for $2.1 billion of the $2.8 billion in Medicare spending for prescription drugs in 1997.

We found that Medicare and its beneficiaries would have saved $1 billion in 1998 if the allowed amounts for the 34 drugs were equal to prices obtained through the FSS. The potential savings for just one drug, leuprolide acetate, accounted for over $275 million. Medicare paid more than double the VA for 14 of the drugs. Overall, it paid between 15 percent and 1600 percent more than the VA for each of the 34 drugs. The biggest difference was for the drug leucovorin calcium, with a VA price of $1.18 and a Medicare price over $20.

In January of this year, we released another report comparing Medicare reimbursement to prices available to the physician/supplier community, the Department of Veterans Affairs, and Medicaid. This time, we studied the prices for 24 drugs which represented $3.1 billion of the $3.9 billion in Medicare drug expenditures in 1999.

We found that Medicare and its beneficiaries would have saved $1.6 billion for these 24 drugs by paying the VA's Federal Supply Schedule price. For half of the drugs, Medicare paid more than double the VA price. The savings would have been $761 million a year by paying the actual wholesale prices available to physicians and suppliers. For every drug in our review, Medicare paid more than the wholesale price available to physicians and suppliers and the VA Federal Supply Schedule price. For example, Medicare reimburses $43 for 10 mg of the drug doxorubicin, more than four times the wholesale price of $10. The VA pays even less, with a Federal Supply Schedule price of $6.29. We also found that Medicare would have saved over $425 million or almost 15 percent a year for the 24 drugs by obtaining rebates similar to the Medicaid program.

We have recently updated the findings of this report with more current drug pricing information. We found that Medicare would have saved $1.9 billion of the $3.7 billion it spent for 24 drugs in 2000 if the drugs were reimbursed at prices available to the VA. Over $380 million of this savings would directly impact Medicare beneficiaries in the form of reduced coinsurance payments. In some cases, the VA price for a drug was less than the amount a Medicare beneficiary would pay in coinsurance. More conservatively, Medicare and its beneficiaries would save $887 million a year by paying the actual wholesale prices available to physicians and suppliers for these 24 drugs. Beneficiaries would pay over $175 million less in coinsurance if Medicare paid for these drugs based on catalog prices. The potential savings to both Medicare and its beneficiaries is probably higher, assuming data for all Medicare drugs is similar to that for the 24 we analyzed.

Nebulizer and End Stage Renal Disease (ESRD) Drugs

In addition to our reports summarizing a number of drugs, we have also produced targeted reports on specific nebulizer and end stage renal disease (ESRD) drugs that Medicare covers.

In June 2000, we released a report which looked at Medicare's reimbursement of albuterol, a drug used with a nebulizer to treat asthma, emphysema, and other respiratory problems. Albuterol is one of the top drugs covered by Medicare, with more than $250 million per year in Medicare allowances. This report updated the findings of several of our prior albuterol studies, all of which noted that Medicare's reimbursement amount exceeded prices available through other sources.

We found that Medicare paid nearly double the Medicaid payment amount and almost seven times what the VA pays for one milligram of albuterol. Furthermore, nearly every pharmacy we contacted sold generic albuterol at prices less than Medicare paid for it. According to our survey results, consumers could go to popular drug stores across the country and buy a monthly supply of albuterol for around $95. For the same monthly supply, Medicare and its beneficiaries would pay a total of $118, with Medicare paying $94 and the beneficiary paying the remaining $24. The VA's entire monthly payment of $17.50 for albuterol is less than just the beneficiary's $24 coinsurance payment under Medicare. We calculated that Medicare could save between $47 million and $209 million per year by setting prices for albuterol equal to those available through these other sources.

Once again, we have recently updated this report with new pricing data. Preliminary findings show that VA prices for albuterol have decreased since last year. The VA price for albuterol has fallen by more than 50 percent over the last 3 years, from $0.11 per mg in 1998 to $0.05 per mg in 2001. During the same time period, Medicare's reimbursement amount (based on reported average wholesale prices) has remained constant at $0.47 per mg.

In 2000, published wholesale acquisition costs for albuterol ranged from $0.09 to $0.18 per mg. These wholesale acquisition costs were provided by manufacturers to drug compendiums such as Red Book. The Medicare reimbursement rate of $0.47 per mg was anywhere from three to five times the wholesale acquisition costs reported by manufacturers.

Recently, we have begun to look at who actually supplies albuterol to Medicare beneficiaries. We found that Medicare reimbursed more than 6,500 pharmaceutical suppliers for albuterol claims in 2000. However, less than 3 percent of these suppliers (184) accounted for approximately 80 percent of albuterol reimbursement. Each of these suppliers had over $150,000 in paid Medicare claims for albuterol last year. Thirty-four of these suppliers were each responsible for more than $1 million in Medicare reimbursement for albuterol in 2000, with five having between $11 million and $35 million in reimbursement. Thus, the vast majority of the albuterol supplied to Medicare beneficiaries was provided by suppliers that purchase and bill for a large quantity of the product. We believe that suppliers that purchase albuterol in such large quantities are likely to receive volume discounts similar to those provided to the VA and other large purchasers. Our work in this area is continuing.

Also in June 2000, we released a report comparing Medicare payments for ESRD drugs to those of the VA and Medicaid. We focused this inspection on five drugs used by renal dialysis facilities to help treat renal failure. These five drugs accounted for $379 million in total charges to Medicare in 1998.

We found that Medicare paid between 37 percent and 56 percent more than the VA for these drugs. Medicare would have saved up to $162 million in 1998 if they paid the same amount as the VA for the five drugs. Furthermore, Medicare paid between 5 percent and 38 percent more than Medicaid. Medicare would have saved as much as $42 million in 1998 by using Medicaid reimbursement amounts.

FLAWED PAYMENT METHOD

Our reports have shown time after time that Medicare pays too much for drugs. Why does Medicare pay so much? We believe that it is because Medicare's payment methodology is fundamentally flawed. By statutory requirement, Medicare's payment for a drug is equal to 95 percent of the drug's average wholesale price (AWP). However, the AWPs which Medicare uses are not really wholesale prices.

For the most part, AWPs are reported by manufacturers to companies that compile drug pricing data, such as First DataBank and Medical Economics which publishes the Red Book. As our reports have indicated, the published AWPs that Medicare uses to establish drug prices bear little or no resemblance to actual wholesale prices available to physicians, suppliers, and large government purchasers.

Aside from the obvious problem of inflated AWPs resulting in inappropriate Medicare payments, the use of AWP also has other potential adverse side-effects. For instance, because physicians and suppliers get to keep the difference between the actual price they pay for the drug and 95 percent of its AWP, this "spread" can serve as an inducement for suppliers or physicians to use one brand of drug product over another. Thus, publishing an artificially high AWP can be used as a marketing device to increase a drug company's market share. Such a tactic would increase the profit of the suppliers or physicians who purchase the drug because, while not paying the artificially inflated AWP amount, they can bill Medicare for it and get paid at that inflated amount. While the published AWP does not increase the amount the manufacturer receives for each unit of the drug product, it may induce an increase in market share because of the higher profits made by physicians and sup-

pliers. This in turn increases the profits of the drug company. All of this occurs at the expense of the Medicare program and its beneficiaries.

For the drug albuterol, the spread is so large and Medicare reimbursement so lucrative that mail-order pharmacies have been tempted to capitalize on the difference by making illegal kickback payments to durable medical equipment suppliers for patient referrals. A civil settlement totaling $10 million has been reached with one pharmacy that succumbed to this temptation.

PHYSICIANS' CONCERNS

Some physician groups have raised concerns about Medicare's attempts to lower reimbursement for prescription drugs. For example, some oncologists have stated that Medicare does not adequately reimburse physicians for the practice costs associated with providing treatment to cancer patients. These physician groups say that overpayments for prescription drugs simply make up for inadequate payments for their practice costs.

We agree that physicians need to be properly reimbursed for patient care. However, we do not believe that the payment of artificially inflated drug prices is an appropriate mechanism to compensate them. We do not think that the decision as to how much Medicare pays for physicians' practice costs should be made by them or by drug manufacturers. The Medicare program or the Congress should have responsibility for this calculation. We certainly do not believe that the basis for their compensation and medical practice expenses should be artificially inflated, misleading, and mis-named average wholesale prices.

The Medicare program already has a procedure for determining and the amount of paying physicians for their practice costs. If the current calculations are incorrect, they should be modified. Physicians deserve fair reimbursement for their valuable services. There is no reason to resort to a make-believe process to accomplish this.

OPTIONS FOR REFORMING THE PAYMENT SYSTEM

There are a number of options for revising Medicare's drug reimbursement methodology. We recognize that there may not be one perfect solution to solving all of Medicare's drug pricing issues. However, we believe these options provide reference points for considering how to reform the Medicare drug payment system.

A few general remarks are in order before discussing specific options. First, some of the options offer a way to calculate a base amount for Medicare reimbursement. These include using the Federal Supply Schedule, the average manufacturer's price, or the AWP, for example. For each such option, additional sub-options are possible. One would be to set Medicare prices at a fixed percentage above or below the base. For example, Medicare currently has its payment rate set at 95 percent of AWP. That percentage could be dropped. Alternatively, if the Federal Supply Schedule were used as a base, then Medicare's payment could be set at, say, 105 or 110 percent of this number.

Second, the options are not necessarily exclusive of one another. In the Medicaid program, most States set payment rates at a percentage below AWP, but they also get rebates from manufacturers. The same could be done for Medicare. Another example might be basing Medicare payment rates on average manufacturer prices (AMP) (used for calculating rebates in the Medicaid program), but making upward or downward adjustments on the basis of surveys of amounts paid by of large institutional health care providers such as hospitals or managed care organizations.

Each option has its own advantages and disadvantages. Some things to consider when comparing them are: the cost of gathering data to set the base, the reliability of the data, the time needed to collect and analyze it; how easily it can be gamed or misrepresented.

Logistical considerations are important too, such as: who will collect and analyze data, who will propose the Medicare payment rate, and how often this will be done; how will the underlying data be verified, by whom, and how often; what method will be used to periodically update the payment amounts, and how frequently will this be done.

Finally, some broader principles and concerns need to be addressed, such as: how proprietary data will be protected; the consequences of drug manufacturers, suppliers, wholesalers, and medical care providers not providing the needed data or misrepresenting it; ways to minimize the burden of public reporting associated with data collection; the need for, nature of, and length of a transitional phase in introducing the new payment method; and whether any adjustment is needed in the practice cost component of Medicare's physician payment rate.

Keeping these factors in mind, the following options may be considered for reforming Medicare's drug payment method:

1. Authorize a commission to set payment rates. A commission could be established similar to MEDPAC, which recommends rate increases for Medicare hospital and physician payments and analyzes prices and economic trends. Such a commission could recommend a periodic update of Medicare prices based on a market basket of drugs, including any new drugs. It would be granted authority to require manufacturers to provide them with drug wholesale prices, but would not disclose any of the proprietary data collected from manufacturers.

2. Calculate national estimated acquisition costs based upon the average manufacturer prices (AMP) reported to the Medicaid program. The Centers for Medicare & Medicaid Services (CMS) could calculate reimbursement rates using AMP and send these rates out to the Medicare carriers. Average manufacturer prices are currently reported to CMS under the drug rebate program, and they more accurately reflect the prices paid by drug wholesalers to manufacturers. If this option were used, it would eliminate the need to go to the manufacturers for more pricing information. This option would require legislation to allow Medicare access to AMP data. Prior to this option being implemented, it would be useful to clarify or refine certain definitions. We also believe an initial, intensive effort should be made to audit AMP data reported by manufacturers to validate its accuracy. We estimate that in the year 2000 Medicare and its beneficiaries would have saved $1.4 billion of the $3.7 billion spent on just 24 drugs if reimbursement for the drugs had been based on AMP.

3. Collect more accurate average wholesale prices from drug pricing catalogs or other sources. This option would entail requiring manufacturers or wholesalers to provide their pricing information or catalogues to an appropriate commission or federal agency. Protection of the confidentiality of proprietary data could be guaranteed in the authorizing statute.

4. Increase the discounting of the published AWP. If this option were used, a provision would be needed to prevent manufacturers from just raising AWP by an amount greater than the newly discounted rate.

5. Base payment on physician/supplier acquisition costs. This option would require obtaining invoices of actual payments made. Payment could not be based solely on the listed invoice price as that price often gets discounted by rebates and volume discounts. Net cost would need to be obtained and this might be difficult because many of the manufacturers rebates are not calculated until the end of the year. Additionally, since Medicare would be reimbursing drugs based on cost there would be little incentive to get the best price.

6. Establish manufacturers' rebates similar to those used in the Medicaid program. A Medicare rebate program could be modeled on Medicaid's program. However, if a Medicare rebate program were used in conjunction with, instead of as a replacement for the current AWP system, then the rebates should be based on AWP rather than the AMP used by Medicaid. This would minimize manufacturers' incentives to inflate AWP because rebates would increase as AWP increased.

7. Create a fee schedule for covered drugs based on the Federal Supply Schedule negotiated by the Department of Veterans Affairs. The payment amounts could be set at the Federal Supply Schedule price or that price plus a certain percentage.

8. Use CMS's inherent reasonableness authority. This authority allows CMS to reduce its payment rates if it can be shown that payment amounts are excessive. A recent study by the General Accounting Office (GAO), mandated by the Congress, found this authority to be appropriate, and it supported some recent studies performed by CMS in its proposed used of it. According to the law which mandate the GAO study, the inherent reasonableness authority may be used as soon as CMS promulgates regulations for it.

9. Use competitive bidding. The CMS currently has the authority to demonstrate the efficacy of competitive bidding for medical supplies. The demonstrations have already proven that inhalation drugs can be obtained at prices lower than 95 percent of AWP. A statutory amendment to make general use of this authority might be appropriate, at least for some categories of drugs, particularly those which are provided by a small number of suppliers or by mail-order firms.

CONCLUSION

There can be no doubt that Medicare pays too much for prescription drugs. This finding has been confirmed year after year. At the same time, Medicare payments overall, including excessive amounts, are increasing substantially. This adversely affects the Medicare trust fund and Medicare's beneficiaries, who are responsible for 20 percent of the bill. While no payment method will perfectly address all conceivable technical problems, many options are available that are superior to the current

payment method, with its misleading nomenclature and artificially inflated prices. Currently, Medicare payments are being set not by the Medicare program but by drug manufacturers and indirectly by health care providers. Until this problem is corrected Medicare and its beneficiaries will unnecessarily pay more and more each year.

I hope this testimony has been constructive in explaining the problem and offering some ideas for its solution.

Mr. GREENWOOD. I thank the gentleman and would note that even if we passed legislation that was signed into law tomorrow, it's probably going to take 6 to 9 months to begin to achieve the saving just because of the bureaucratic necessities.

The Chair recognizes Mr. Zachary Bentley, President of Ven-A-Care Inc., for your testimony, sir.

TESTIMONY OF ZACHARY T. BENTLEY

Mr. BENTLEY. Mr. Chairman, members of the subcommittee, good morning. I am Zachary T. Bentley. For the last 13 years, I've been an officer and a business manager of Ven-A-Care of the Florida Keys, a small pharmacy located in Key West, Florida. Early on, I was shocked to receive a payment from Medicare for the infusion cancer drug Leucovorin that exceeded our costs by approximately 1,000 percent.

Mr. GREENWOOD. Mr. Bentley, could you pull the microphone just a little closer, please?

Mr. BENTLEY. The tenfold profit on this drug being paid for by Medicare was so excessive that the beneficiary's 20 percent copayment actually exceeded the cost of the drug to Ven-A-Care.

I attempted to return the payment, only to learn that the Medicare carrier did not believe it had made a mistake. The prices used by Medicare, Medicaid and many private health insurers for setting drug reimbursements are the prices reported to those entities by drug manufacturers. We have discovered that some, not all, drug manufacturers report falsely inflated prices so that their customers will reap exorbitant windfall profits.

In 1991, Ven-A-Care was solicited to enter into a physician joint venture designed to split the proceeds of such excessive reimbursements with doctors in a position to prescribe expensive infusion drugs to AIDS patients. The venture was crafted by one of the country's largest health care companies, National Medical Care, then a subsidiary of W.R. Grace. We were promised by NMC that we would become wealthy if we cooperated. We refused because we believed that this proposal was nothing more than a kickback scheme, which would ultimately lead to overutilization of drugs and possibly patient harm.

National Medical Care then proceeded with the physician joint venture on its own and effectively ran Ven-A-Care out of business. Later when Ven-A-Care attempted to rebuild its business with a focus on oncology drug therapies, we encountered demands that we enter into a similar kickback arrangement with oncologists associated with yet another large national health care company. Again, we declined to participate. Instead, we redoubled our efforts to shine the light of day on these shadowy schemes.

We have worked diligently to educate those who administer Medicare and Medicaid programs about this serious problem, including personally briefing the previous HCFA Administrator. We

have assisted the HHS Office of Inspector General, the Department of Justice, and have prosecuted false claims actions that resulted in the government's nearly $500 million recovery against National Medical Care and the more recent $14 million Medicaid settlement with Bayer Pharmaceuticals Corporation. We also initiated the pending Texas Medicaid false claims action against inhalation drug manufacturers Warrick, Roxane and Dey Laboratories. Texas Attorney General John Cornyn has joined with us in that case.

Last year we were subpoenaed by your committee to provide our information relating to this drug pricing fraud. The information we provided reveals some troubling things. A fraud scheme costs the government billions of dollars each year and encompasses not only chemotherapy drugs, but drugs used for inhalation, biologicals, IV fluids, IV antibiotics, and now it is in the community retail marketplace.

Medicare and Medicaid patients are harmed when health care providers' decisions to prescribe and dispense drugs are based on profit rather than the best interest of the patient. The fraud adds to the spiralling Medicaid drug expenditures that have forced some States to curtail other needed public health services. Medicare patients are defrauded because their 20 percent copayment alone often exceeds 100 percent of the true cost of the drug.

Americans are being deprived of newer and safer drugs when manufacturers inflate price reports of newer drugs to encourage physicians to keep prescribing the older drugs. Government programs are deprived of the benefits of vigorous price competition when expensive drugs become subject to competition by generics, other patented drugs or other kinds of treatments. Prices drop in the marketplace, but prices reported to the government remain at the same level or in some instances actually rise. Those drug manufacturers making false price representations have effectively usurped the right and duty of Congress to determine Medicare drug payments and the right and duty of your State legislators and Congress to determine Medicaid drug payments. Our existing Medicare drug reimbursement system is broken only because some, not all, drug companies have chosen to falsely report inflated prices.

And finally, no expanded Medicare drug benefit can successfully be implemented unless drug companies are required to tell the truth about their prices.

Thank you very much. I'll be happy to answer any questions.

[The prepared statement of Zachary T. Bentley follows:]

PREPARED STATEMENT OF ZACHARY T. BENTLEY, PRESIDENT, VEN-A-CARE OF THE FLORIDA KEYS, INC.

Mr. Chairman and Members of the Subcommittees: Good morning. I am Zachary T. Bentley.

For the last thirteen years I have been an officer and the business manager of Ven-A-Care of the Florida Keys, a small pharmacy located in Key West, Florida. Early on, I was shocked to receive a payment from Medicare for the infusion cancer drug, Leucovorin, that exceeded our cost by approximately 1000%. The ten-fold profit on this drug, being paid for by Medicare (80%) and the beneficiary (20%), was so excessive that the beneficiary's co-payment actually exceeded the cost of the drug to Ven-A-Care. I thought the Florida Medicare carrier had made a mistake. I attempted to return the payment, only to learn that the Medicare program in fact assumed that the cost of Leucovorin was many times greater than the true price available to even a small company such as Ven-A-Care.

We communicated pricing information about Leucovorin and other drugs which we discovered had similar pricing and reimbursement disparities, to the Health Care Financing Administration and other federal and state agencies, in an effort to alert them to the problem. We learned that the prices used by Medicare, Medicaid, and many private health insurance programs for setting drug reimbursements were the prices reported to those entities by the drug companies. When the manufacturers report falsely inflated prices, providers reap exorbitant windfall profits. Those windfall profits serve the drug manufacturers as government-funded kickbacks to induce the providers to order their drugs.

I must emphasize, however, that not all pharmaceutical manufacturers engage in this nefarious scheme.

In 1991, Ven-A-Care was solicited to enter into a physician joint venture designed to split the proceeds of such excessive reimbursements with doctors in a position to prescribe expensive infusion drugs to AIDS patients. The venture was crafted by one of the country's largest healthcare companies, National Medical Care, then a subsidiary of WR Grace. We were promised by NMC that we would become wealthy if we shared drug revenues with the treating physicians, because they would order large quantities of pharmaceuticals that cost far less than the reported prices. We believed that this proposal was nothing more than a kickback scheme, which ultimately would lead to over-utilization of drugs and possibly to patient harm, and we elected to not participate. National Medical Care then proceeded with the physician venture on its own and effectively ran Ven-A-Care out of business.

Later, when Ven-A-Care attempted to rebuild its business with a focus on oncology drug therapies, we encountered demands that we enter into similar kickback arrangements with oncologists associated with yet another large national healthcare company. Again, we declined to participate. Instead, we redoubled our efforts to shine the light of day on these shadowy schemes.

We learned that almost every third-party payer, including Medicare, Medicaid, the Federal Employees Health Benefits Plan, and most private insurers, relied on the drug companies' representations of drug prices when setting the reimbursement amounts paid to providers. It became apparent to us that many drug manufacturers reported truthful prices, while others falsely inflated their price reports so that their targeted customers—oncologists, urologists, home care companies, ESRD providers, DME companies, and others—would be induced by the resulting windfall profits to order their drugs.

We have worked diligently to educate those who administer the Medicare and Medicaid programs about this serious problem, including personally briefing the previous HCFA Administrator. Ven-A-Care also has taken direct action to stop this major hemorrhage of tax dollars. We have assisted the HHS Office of Inspector General and the Department of Justice and have prosecuted False Claims actions that resulted in the government's nearly $500,000,000 recovery against National Medical Care/Fresenius and the more recent $14,000,000 Medicaid settlement with Bayer Pharmaceutical Corporation.

We also initiated the pending Texas Medicaid false claims action against Schering Plough's Warrick drug division, Boehringer Ingelheim's Roxane drug division, and Dey Laboratories. Each of those companies manufacture inhalation drugs used to treat severe respiratory ailments. Texas Attorney General John Cornyn has adopted our claims, and we are currently assisting him in that litigation. The Texas Medicaid Program has led the Nation in its efforts to secure accurate price reports from drug companies by requiring written certification of a range of prices.

Last year, pursuant to subpoena, we provided to the House Committee on Energy and Commerce our documents and other evidence relating to the inflation of price reports by certain drug companies. In preparing for my testimony today, I have again reviewed the information now in the Committee's possession. The Committee's commendable oversight and investigative efforts have alerted the Congress and the public to the following issues:

1.) The evidence reveals that the fraud scheme encompasses a wide range of drugs including chemotherapy, inhalants, biologicals, IV fluids, and, IV antibiotics. More recent reports reveal that the fraud is also directed at oral drugs reimbursed by Medicaid and which will be the focus of an expanded Medicare drug benefit.

2.) Falsely inflated drug price representations enrich certain health care businesses, including some drug companies, home care pharmacies, oncologists, and inhalation providers, while cheating Medicare beneficiaries of their current drug benefits. This shameful fraud levies a cruel tax on Medicare beneficiaries, whose 20% co-payment alone often exceeds 100% of the true, reasonable cost of the drug to health care providers.

3.) This fraud compromises the health and safety of Medicare and Medicaid patients. The excessive reimbursements are used as inducements to physicians and other health care providers in a position to cause the companies' drugs to be ordered. Oncologists and other providers are thus financially induced by certain drug manufacturers to prescribe such vital drugs as chemotherapies, not on the basis of what is best for the patient, but based on what is most profitable for the medical provider. Such kickback schemes impair independent medical judgment and interfere with the physician/patient relationship. A case in point involves the prostate cancer drug Lupron, manufactured by TAP Pharmaceuticals, a joint venture between Japan's Takeda Pharmaceutical Company and Abbott Labs. Recently announced criminal indictments of several urologists illustrates the seriousness of the problem.

4.) The price fraud costs Medicare and Medicaid billions of dollars each year in the form of excessive reimbursements and over-prescribing of medications.

5.) False, inflated drug price representations effectively deprive Medicare and Medicaid patients of access to medical care because:

a.) Seniors are overcharged in their co-payments and thus have less money available to purchase other needed drugs not covered by Medicare.

b.) Scarce health care program dollars are diverted to fund these overpayments and kickbacks that benefit practice specialties in a position to increase drug company sales. The Wall Street Journal reported last February 7 that "states say the drug-cost component of Medicaid is rising more than 20% annually," forcing states to cut funding for other services. Missouri budget director Brian Long told the Journal that Medicaid costs are responsible in part for his state's inability to fund increased costs for school transportation and special education. An Ohio budget official said "The rest of state government is dramatically impacted" by rising Medicaid drug costs. Similarly, scarce Medicare dollars are diverted and thus not available, therefore, to increase reimbursements to other practice specialties such as cardiology, surgery, and gynecology.

6.) Certain drug manufacturers and health care provider groups have actively misled Congress and the Medicare and Medicaid programs in an effort to conceal and perpetuate this fraud. Examples include

a.) Seeking to deflect scrutiny by contending that Congress and the Executive Branch have created a flawed reimbursement system. This argument is specious, because the system works well as long as drug companies tell government insurance programs the truth about their prices. If a flaw exists, it is the fault of the drug companies who choose to give the government false prices.

b.) Contending that the inflated reimbursements are needed to defray other provider costs not adequately covered. Some health care providers may be justified in requesting higher reimbursements. The recent GAO study, however, will confirm that the drug companies in question (and I reiterate that not all drug companies are guilty of this practice) have generated exorbitant reimbursement schedules for certain drugs. The scheme benefits only the companies and their provider customers, to the detriment of government health insurance programs and patients. These inflated reimbursements are created only when a drug company desires to fend off competition; they are not calculated to cover administration costs, and they far exceed any reasonable level of reimbursement.

c.) Some health care professionals have stooped to extortion tactics by threatening that they cannot continue to care for cancer patients if their gravy train is derailed. The false premise for this threat is revealed by the fact that those same health care professionals were making the drugs available to patients before manufacturers contrived to create such lucrative "spreads" to stave off competition by other manufacturers.

I find it offensive that the drug companies that are engaging in these practices have tried to conceal their actions while at the same time piously holding themselves out as stewards of the public good. In fact, the sub-committees' subpoenaed records reveal that one major drug manufacturer inflated price reports for a broad range of cancer drugs while touting itself as America's "most admired" pharmaceutical company.

7.) The federal government and many states have taken action to improve reimbursement systems by requesting additional price data. For example, California often bases payments on manufacturers' reports of direct prices and submission of manufacturer invoices; Texas requires written certification of different kinds of prices and costs; many States rely on reports of Wholesaler Acquisition Cost rather than AWP; HHS regulations were modified to provide for a federal Med-

icaid Upper Limit; and Congress enacted the Medicaid rebate law. Each of these efforts, however, has been circumvented and frustrated by certain drug companies that falsely inflate any form of price or cost data the government attempts to use to set reimbursements.

8.) The fraud scheme deprives government programs of the benefits of vigorous price competition that occurs when expensive drugs become subject to competition by generics, other patented drugs, or other kinds of treatments. Prices drop in the marketplace, but prices reported to the government remain at the same level, or rise. As a result, Medicare, Medicaid and the public are misled to believe that the drugs remain highly expensive when in fact they sell for a fraction of their pre-competition prices. The current example of the cancer drug Taxol is illustrative. When Taxol's patent protection expired recently and a competing generic drug entered the market, the prices of both drugs began to fall. Nevertheless, the reported prices remained at the pre-competition level, creating a "spread" that is used to market both drugs, and government health insurance programs have not benefitted from the reduced (but unreported) prices set by the marketplace. It is ironic that there was no "spread" before Taxol had a generic competitor, but now a "spread" exists and is used to market both drugs.

9.) Those drug manufacturers making false price representations have effectively usurped the right and the duty of Congress to determine Medicare drug payments, and the right and duty of state legislatures and Congress to determine Medicaid drug payments. Increased oversight by the Congress and enforcement by the Executive Branch, have resulted in at least two drug manufacturers reporting markedly lower prices to the Medicaid Programs, however, even those companies continue to report inflated prices for Medicare purposes.

After concluding the first stage of its investigation last year, Congress enacted legislation requiring the General Accounting Office to investigate and report on the true costs of the drugs in question and the expenses incurred by health care providers in administering them. The legislation also requires the recently renamed Center for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA), to review the GAO report when issued and take appropriate action with respect to Medicare drug reimbursements. State Medicaid programs already have taken actions based on the results of investigations by the Department of Justice and the National Association of Medicaid Fraud Control Units, and many of those programs have already reported saving tens of millions of dollars as a result. I am hopeful, that after considering the GAO report, CMS Administrator Thomas Scully will take similar action to stop these excessive payments that are costing the Nation's health care systems billions of dollars each year.

In conclusion, the evidence amassed by the sub-committees demonstrates without doubt: No drug reimbursement system will succeed unless drug companies tell the truth about their prices. Our existing Medicare Drug Reimbursement System is broken because certain drug companies lack honesty and integrity. Any expanded drug benefit will be doomed to fail if those same companies continue to lie about their prices.

Thank you for the opportunity to bring to the sub-committees' attention this widespread, institutionalized fleecing of Medicare, Medicaid and other health care programs funded by the American taxpayer.

I will be happy to answer any questions the sub-committees may have.

Mr. GREENWOOD. Thank you for your testimony.

The Chair recognizes himself for 5 minutes for questions, and would refer to document N1 and ask the staff to have that projected. That's the document that was projected earlier.

N1. Staff, N1. There we go.

Let me start with you, Mr. Bentley, and let us look on that chart at Mitomycin. Mitomycin is what kind of drug, Mr. Bentley?

Mr. BENTLEY. It's a chemotherapy agent.

Mr. GREENWOOD. It's a chemotherapy agent.

Let me understand—let me make sure that I understand and we all understand this chart. Your company, Ven-A-Care, the one to purchase that drug, at catalog price from the manufacturer would pay $180. Is that correct?

Mr. BENTLEY. Yes, sir.

Mr. GREENWOOD. Okay. And the Red Book, the document that Medicare uses in order to determine the reimbursement to the physician, then is posted by the manufacturer at $869.33. Is that correct, sir?

Mr. BENTLEY. That is the Medicare allowable, which would be 95 percent of the AWP that is posted in the Red Book.

Mr. GREENWOOD. So Medicare pays $869 to the physician for a product that he paid $180 for—95 percent of that?

Mr. BENTLEY. Correct.

Mr. GREENWOOD. So the overpayment is in the vicinity of 680 some dollars Medicare is overpaying for that drug?

Mr. BENTLEY. Yes, sir.

Mr. GREENWOOD. Now, let us look at the impact of that particular chemotherapy drug on the patient. The patient's requirement under Medicare is to pay 20 percent, 20 percent copay. If, in fact, the copay was based on the—what was actually paid for the product, I would assume that that would be a $36 cost. Is that correct?

Mr. BENTLEY. Yes, sir.

Mr. GREENWOOD. Okay. Instead, the copayment is $173.86, which I would calculate is $137 more than the patient should pay in copayment. So the patient gets ripped off for $137. And whether or not we believe that the oncologists—and I do believe that the oncologist needs to recover more than we're paying him now. I'm looking at the patient here. What if the patient doesn't have the $173.86? What if the patient could afford $36 for the treatment, but doesn't have the $173. What happens?

Mr. BENTLEY. That's correct.

Mr. GREENWOOD. The patient could conceivably do without treatment.

Mr. BENTLEY. That's correct. Or other family members may have to help pay the successive copayment amount, which only puts a burden on other family members when a loved one has cancer. And I would also say that Mitomycin is also paid to pharmacies by the DMERC's under Medicare, not just oncologists.

Mr. GREENWOOD. Let me pose this question to Mr. Scanlon. Mr. Scanlon, the crux of this whole—there is no question that AWP system is broken. I've talked to every pharmaceutical company that I could find. They all agree. I've visited my own oncology doctors in my county. They agree that the system doesn't—that the system doesn't make sense as it's constituted. There is this question of whether the oncologists in particular and other providers are undercompensated and what we need to spend to pay them fairly.

Is it your testimony that—what was the figure in your report for the overpayment to oncologists for these drugs? What was that number?

Mr. SCANLON. It's approximately $530 million.

Mr. GREENWOOD. $530 million——

Mr. SCANLON. Based on the conservative estimate of——

Mr. GREENWOOD. $530 million per year, half a billion dollars a year just for oncological products.

And, sir, what does your study reveal as to what it would cost to bring oncologists up to the rest of the medical profession in terms of the way they're compensated by Medicare?

Mr. SCANLON. There are a number of elements in that. I mean, to put the oncologist on par with other physician specialties, first of all, there's the issue of the adjustment of their fees for chemotherapy administration and the substitution of an alternative method for the basic method. Restoring the basic method would add about $31 million to their payments.

Oncologists have also raised issues about an adjustment that HCFA made in terms of their supplies, and they've indicated that they believe that HCFA has reduced their supply estimates too much in terms of taking the drug costs out of what was reported in the survey data used to set up the fee schedule. We don't have a firm estimate of what supply expenses should be. The oncology profession has indicated that it should be about double of what HCFA uses, which would add another $20 million to oncology payments.

Other issues that they raise, we cannot make an estimate now as to what impact that might have on their fees, and as I indicated, they might not have a big impact at all because other specialties might have the same types of issues, in terms of practice expense, keeping pace with changes in practice.

Mr. GREENWOOD. My time has expired. The Chair recognizes the gentleman from Florida Mr. Deutsch for 5 minutes.

Mr. DEUTSCH. Thank you, Mr. Chairman.

Mr. Scanlon, if I can follow up on that, because I think one of the interesting things in your very, you know, insightful testimony was really this whole issue of the alternative approach. I mean, there's a clear consensus it's broken. How do we fix it? I mean, specifically, if you can elaborate. You were starting to elaborate in terms of the physicians themselves, the reimbursement, the AWP reimbursement. I mean, can you offer some specific suggestions to us?

Mr. SCANLON. Well, in terms of the physician payments for chemotherapy administration and other services that don't involve a physician directly, to restore the basic method, what it means is that you use differences in the resources—the types of inputs—that are needed to provide a different service as the basis for determining Medicare fees. The alternative method that was used by HCFA involved the substitution of historical charges, what physicians actually charge, and which oncologists have said were based on the past and do not reflect current experience or practices in the delivery of these kinds of services. So we believe in substituting information about actual resources that are required, that HCFA has developed through expert panels and may need to update through additional expert panels to keep current, but that kind of information is key to put the physician fees on par with——

Mr. DEUTSCH. If I can follow up on that, your study points out almost a 10-to-1 differential between hat government—what we would save or what Medicare would save if we changed up AWP versus switching the physician payment. The oncologist group—and I don't know if they are going to testify to this later, but I'm aware of at least a study that they did, not as extensive as yours, which was saying it was almost a 1-to-1 tradeoff. Have you looked at their study, and how do you respond?

Mr. SCANLON. We have looked at their study. We have not been able to replicate their study, but at the same time we have concerns about the method of the study. I mean——

Mr. DEUTSCH. That is obviously a pretty big differential.

Mr. SCANLON. There is no question about it. There's a number of differences in terms of what we've done and what they have done. We have built this estimate based upon all the services physicians provide, which we think is key to understanding this problem. The physician fee schedule is a relative value fee schedule. It sets fees for one service based on the comparison of the resources required for it versus other services, and it distributes an amount of money that we found to be adequate in order to get physician participation in Medicare. So that's the criteria for setting physician fees.

To build an estimate of expenses from looking at individual procedures is not nearly the same, because what it ignores is the fact that the fees that become paid to a physician includes three components. One is the practice expense component. The second one is the physician work component, for which there is no comparable sort of accounting cost, and that accounts for over half the fee. And the third thing is the malpractice expense component. So in some respects it becomes—when you start to look at this as a piece, you have the potential of being misled, and it's much more important to look at this in the aggregate.

Mr. DEUTSCH. If I can sort of open this up to each of you individually, and let me also welcome Mr. Bentley as a constituent. I'm glad you made your way up to Florida. It's not as easy—from Florida. It's not as easy as it used to be. Hopefully that will change.

But in my opening statement I mentioned what I think in some ways is as big, if not the biggest, concern is the substitution based on market forces, and we all can, you know, come up with theories that it's going on. Do we have empirical or even anecdotal evidence that, in fact, there has been substitution based upon the increased spread of particular drugs? I mean, do we have either anecdotal or empirical evidence, besides theoretical evidence, which clearly we do have? If you don't know, that's fine.

Mr. BENTLEY. I believe there is evidence that——

Mr. DEUTSCH. Can you point to anything specific that you're aware of?

If you can pull the mike closer as well. It gives—I mean, we can all see that it should be occurring, or it could be occurring. Obviously we hope it's not occurring.

Mr. BENTLEY. This was part of a drug I was referring to in my opening statement, which is a new version of an older drug called Vepesid, which is——

Mr. GREENWOOD. Mr. Bentley, why don't you lift your microphone up. I know everyone wants to hear you. And make it—speak as directly into the microphone as you can. Point it toward your——

Mr. BENTLEY. Okay. This is an internal Bristol-Myers Squibb document that shows Etopophos, which is a second-generation etoposide that was developed, and they say that it's clearly superior to that of etoposide and for various reasons. And then they go on to the next document, where it says, the Etopophos product pro-

file is significantly superior to that of etoposide. Now, what they were concerned about was there was a big spread already in etoposide, so how were they going to market and sell the better, in their own words, clinically superior, second-generation drug?

Now, they admit right here, currently physician practices can take advantage of the growing disparity between Vepesid—that's etoposide—list price and subsequently the average wholesale price, AWP, and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physicians' financial incentive for selecting the brand is largely diminished.

And they go through some different scenarios. And I can tell you right now that the spread differential on etoposide, as was pointed out earlier, Medicare is reimbursing approximately $135 for the old version of etoposide, and it costs less than $10. And literally we have a, quote, clinically superior drug that Bristol-Myers Squibb has been unable to market because of the spread on the older version of the drug.

Mr. GREENWOOD. Your time is——

Mr. DEUTSCH. Can I just ask a very short follow-up question?

Mr. BENTLEY. Sure.

Mr. DEUTSCH. And I know my time is expired. I guess I have a copy of this, and it's up there. I'm just curious. You were able to ascertain this information through your whistleblower lawsuit. How were you able to——

Mr. BENTLEY. This—I obtained this from the Justice Department, cooperating with them. They obtained this by an OIG subpoena issued to Bristol-Myers Squibb.

Mr. GREENWOOD. The time of the gentleman has expired.

The Chair recognizes for 10 minutes the gentleman from Florida, the chairman of the Health Subcommittee, Mr. Bilirakis.

Mr. BILIRAKIS. Thanks, Mr. Chairman.

Mr. Bentley, the Mitomycin that's on that chart, 40 milligram, and the dollar figures attached thereto, how many doses is that? Is that one dose?

Mr. BENTLEY. Well, that's one vial. Depending on how it is administered, that could take two or three vials to equate to a dose.

Mr. BILIRAKIS. All right. So if it took 2 or 3 vials for one dose——

Mr. BENTLEY. You multiply all of those figures times 2 or 3. And if I can interject to shine some light on some previous remarks that were made, the Mitomycin, that AWP, that was established by the drug manufacturers, and that is what Medicare is relying on to determine the reimbursement. And I can tell you I have examined tens of thousands of internal drug company documents, and there is not one scintilla of evidence that shows that the drug companies established an inflated price for Mitomycin in order to offset practice expense for oncologists or to give the pharmacists any more money. It just—that is not the focus.

Mr. BILIRAKIS. So who created the AWP, then? Is it created by HCFA, by HHS, by——

Mr. BENTLEY. It's been around, sir, for the better part, that I'm aware of, about 40 years. And for a great number of those years, it's always worked, and there are still a great number of companies, Merck, Lilly, Johnson & Johnson, DuPont, who do not engage

in this type of gaming the system. When they make a representation about the price of the drug, you may not like it because it may be high, but that's the price they sell it for.

Mr. BILIRAKIS. Let me ask you, about the $180 figure which is the Ven-A-Care cost. Is HCFA, in your opinion, aware that that's really all that it cost?

Mr. BENTLEY. I think they are now, sir.

Mr. BILIRAKIS. Mr. Scanlon, are they aware of it?

Mr. SCANLON. Yes, Mr. Chairman.

Mr. BILIRAKIS. Have they been aware of it?

Mr. SCANLON. They have been aware of it, and last year they did take steps to try and change this, but then because of concerns raised by providers, they backed off and——

Mr. BILIRAKIS. Concerns raised by providers to HCFA?

Mr. SCANLON. About the imbalance between the drug prices and the drug administration compensation.

Mr. BILIRAKIS. Concern was raised by providers, being——

Mr. SCANLON. Yes, sir.

Mr. BILIRAKIS. [continuing] let us say in that case the oncologists?

Mr. SCANLON. Yes, sir.

Mr. BILIRAKIS. Mr. Grob, do you agree with that?

Mr. GROB. That's correct.

Mr. BILIRAKIS. Because concerns were raised by providers, it just remained status quo?

Mr. GROB. The status quo has remained. In fact, the Congress required that it remain that way.

Mr. BILIRAKIS. That's what I want to get to. The Congress did what?

Mr. GROB. The Health Care Financing Administration had advocated making available more realistic drug prices to the carriers, but because of the concerns that were raised, the Congress placed a moratorium on any reductions in those prices, and it commissioned the study of the General Accounting Office.

Mr. BILIRAKIS. And that's what we have today. I'm almost speechless.

Is there a substitute or an equivalent drug that will do the same job Mitomycin will do? Mr. Bentley?

Mr. BENTLEY. I'm not a pharmacist. I'm not—I don't know. Really my expertise is on pharmaceutical pricing and the economics.

Mr. BILIRAKIS. Do any of you know?

Mr. GROB. I don't know, Mr. Chairman.

Mr. SCANLON. Nor do I.

Mr. BILIRAKIS. Mr. Grob, do you know, can HCFA, the administration, HHS, et cetera, et cetera, can they fix this in a way that it should be fixed? You know, and I'm not—I realize this is more complex. It's certainly not a simple situation, but can they fix this? Do they have the power to fix this, or does it have to be Congress?

Mr. GROB. Theoretically, CMS does have the power through an authority called their "inherent reasonableness" power, which allows them to conduct studies to determine what the true prices are, and if there is a price that is, as the phrase says, inherently unreasonable, they can reduce it. However, that's a very lengthy process to conduct the studies. The studies are almost——

Mr. BILIRAKIS. Yeah. But then we get the figures up there, the 7 cents for the one and 94 cents for the $1.20. What kind of studies are we talking about?

Mr. GROB. Well, they would be studies to determine what the market prices are, what comparable prices are.

Mr. BILIRAKIS. But those are the prices, aren't they?

Mr. GROB. We believed for some time that there's good, strong evidence for reducing those prices, and CMS would have that authority. And, in fact, CMS had the means even just by making the prices available to the carriers to do it, but there has always been resistance to this.

CMS to its credit in the past had advocated other ways to deal with the high prices e.g., to increase the discount on the AWP, but these proposals——

Mr. BILIRAKIS. I guess my time did expire. I'm sorry, Mr. Chairman. I didn't notice that.

Mr. GREENWOOD. Thank you.

We are going to collect a dollar for the firefighters of New York for everyone who says HCFA for the remainder of this hearing.

Is the gentleman Mr. Brown available for questioning now?

In that case, the gentleman from New Jersey Mr. Pallone. He's recognized for 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman, and, Mr. Bentley, I just want to continue with some of these documents in an effort basically to show that, you know, companies consider doing what's right, but then they choose to do what's wrong, so to speak. And if I could ask that we successfully look at, I guess, B-1, B-2 and B-3, and we'll start out with B-1, which is an internal Glaxo document. And I just wanted to—you know, Mr. Bentley, if you just wanted to comment on that first document in this regard.

Mr. BENTLEY. Sure. This is very interesting. Glaxo was the first company to market the antiemetic Zofran that's used to control nausea and vomiting in chemotherapy patients. And they had a natural monopoly for a number of years, because they had the only drug that was FDA-approved for this indication. And in approximately 1995, SmithKline came out with a competing drug, not a generic, but a drug that was effectively controlling nausea and vomiting. And Glaxo noticed that their market share declined dramatically right from the onset of the introduction of Kytril. Now, they expected obviously they were going to lose some market share, because there was competition in the marketplace. They didn't expect to lose the amount that they had lost so rapidly. And the marketing department told Glaxo, well, it was an easy answer. Physicians were actually being courted by SmithKline representatives to switch from Zofran to Kytril based on the opportunity to make money from Medicare and Medicaid.

So they came up on some proposals on how they were going to level the field and this was an internal memorandum. Obviously somebody with some conscience in Glaxo was concerned about the ramifications of what Glaxo was proposing to do and that was to raise the net wholesale price in AWP, which would effectively increase the amount paid by Medicare and Medicaid while simultaneously lowering the price to physicians and to specialized pharmacies like Ven-A-Care in order to create a spread to compete with

SmithKline's competing product, and that spread that they were going to compete with was not their own money. It was the government funds being used to fund a kickback essentially for their marketing efforts to compete with SmithKline, and they were obviously very concerned about what Congress was going to look at.

Mr. PALLONE. This was the second document, right, B-2? Oh, we are still in B-1, okay.

Mr. BENTLEY. The next document shows what Ven-A-Care received in the mail from Florida Infusion announcing this great revolution, and that was Glaxo had raised the AWP but lowered the price, effectively creating a spread to induce Ven-A-Care and physicians to go back to Zofran for those that were using the competing Kytril.

Mr. PALLONE. Then let us go to B-3. This is the Smith Kline document where, I guess what is it called, Health IQ, where they talk about possibly turning Glaxo into Medicare and that that might be a reasonable approach but then they worry about the whole industry going down. Do you want to comment on that?

Mr. BENTLEY. Yes. This is interesting because there was actually a series of letters written by Health IQ under the letterhead Physician Home Care Associates, and they were written to every medical director of the Medicare Part B carriers and to the Medicaid medical directors and they were ostensibly representing themselves as this great group that represented home care doctors and pharmacies. However, it was nothing more than a lobbying group that was being paid for by SmithKline, and if you look at bullet point No. 4 it says from the communication received to date the letters received by Physician Home Care Associates, ostensibly written on behalf of physicians and other health care providers, appear to be greatly appreciated by the medical director. That is the Medicare Part B directors. A follow-up letter apprising Medicare of an increasing in Glaxo's AWP and a proffered discount to purchasers which would seem to benefit providers might appear peculiar and prompt questions as to the true identity of Physician Home Care Associates." And then they go on that they——

Mr. PALLONE. Read that next section.

Mr. BENTLEY. Sure. "As a result of these issues raised above, Health IQ's concern that highlighting the difference between the actual acquisition cost and the published AWP may not only increase attention to Glaxo's pricing practices but may provide the impetus for HCFA to implement a system that could impact not only reimbursement of antiinfectives but all pharmaceutical and biological products. The ramifications could extend well past Medicare to include Medicaid programs also administered by HCFA as well as private payers who tend to mimic policies and procedures implemented by public payers."

Mr. PALLONE. Obviously that was the point that they were concerned that the whole industry was going to go down.

Mr. BENTLEY. Absolutely.

Mr. PALLONE. Thank you. Thank you, Mr. Chairman.

Mr. GREENWOOD. Thank you. I recognize for purposes of inquiry the chairman of the full committee, Mr. Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman. First let me respond to concerns that we have somehow questioned the motives

of any physicians involved in this payment system. First of all, the concerns expressed by oncologists as we have reviewed this matter was to the effect that if we did not simultaneously repair the deficiencies in practice reimbursements under the Medicare system while we are curing the unfairness of the system that reimburses way beyond the cost of the medicines that are provided to Medicare patients that we would be disrupting the provision of health care services to patients in America. That is a real concern of this committee, and so let me turn quickly to the—I guess to the first question for the GAO. The numbers you have submitted to us is that practice reimbursements are about $51 or so million dollars short; is that correct.

Mr. SCANLON. The adjustments that we think should be made would approximate that.

Chairman TAUZIN. I understand Mr. Scully is going to put a figure of about $48 million or so. It seems the two of you are close, but even if you multiply the numbers you have given us by three, if you provided reimbursements to the physicians three times what you estimate is a shortfall at $150 million, we are still talking about overpayments of a billion dollars. So if we correct the overpayment problem in the system because of this artificially high AWP wholesale price posting, there is ample room, then, to correct the deficiencies that you and Mr. Scully have found in the payment to physicians for services; is that correct?

Mr. SCANLON. That is correct.

Chairman TAUZIN. So that in correcting this problem, if we handle it properly, if we make adjustments for physicians' practices three times as much as you estimate is a shortfall, we could still save the system $850 million or more each year in the overpayments for these drugs; is that correct?

Mr. SCANLON. That is correct, but I would also note, Mr. Chairman, the changes that we have talked about in terms of implementing the fee schedule as you have specified do not involve an additional expenditure because the fee schedule has been budget neutral. If you decide to increase——

Chairman TAUZIN. The problem there is it would come out of other physicians' reimbursements. So if we added to that pool, three times what you recommended as the deficiencies paid to these physicians so that it could be spread out more equitably without denying other physicians their reimbursements, we would still save $850 million to the Treasury in the——

Mr. SCANLON. You could still save considerable money.

Chairman TAUZIN. Let me turn to the other issue that disturbed me so much, and I want to tell my friends Mr. Ganske and Mr. Norwood that I didn't make these comments lightly and I stand by them. I am looking at the IG report now that is number Q-1. It contains some rather chilling language. It says in that report a review of 22 skilled nursing facilities, that at these facilities $4.8 million out of the $9 million in claims, 53 percent were not medically necessary. They went on to say that in addition financial effects we noted about overutilization and overpricing were potentially harmful to the patients. "Medical reviewers who were part of our audit"—this is a quote. "Medical reviewers who were part of our audit concluded that patients receiving unnecessary infusion serv-

ices were placed at undue risk for complications," and it went on to say, "Furthermore, infusion services are invasive procedures that are painful and when unnecessary reduce the quality of life."

That IG study, did it not, also went on to say that maybe one of the inducements for this overutilization was this crazy system where overreimbursements were provided for some of these infusion drugs?

Mr. GROB. Again, we didn't tie analytically the two together, but the thing that concerns me is that it is in the air. I think where we want to be—I think we would all feel better if it just wasn't that big of a possibility.

Chairman TAUZIN. That is the point. Let me try to say it maybe a little more accurately, as you have tried to say it, Mr. Grob. The fact that these overpayments are there next to the fact that there is evidence not only in that study but in one reported by the New York Times on May 13, 2001 indicating how much overuse of chemotherapy seems to occur in some cases in the last stages of some cancer patients' lives when there is strong medical evidence that the chemotherapy had no effect at all upon the quality of life or the treatment of the cancer, that these studies standing out there with this overpayment system also present, if nothing else, creates the image that something is wrong and that is bad and the notion that anyone in this country would be given infusion drug therapies that would harm them or could possibly harm them or make life less pleasant for them in those last days with a system that overcompensates for doing that is a juxtaposition that we ought not to permit. Isn't that a point in your study?

Mr. GROB. It is. We feel that we all wish you would not have to ask me that question.

Chairman TAUZIN. Exactly, and I am going to quote you. Abusive billing arrangements between the skilled nursing facilities and infusion suppliers resulted in tremendous profits, and here is your quote, "which encouraged the overutilization of infusing services when no treatment was necessary." You did tie it together.

Mr. GROB. Yes.

Chairman TAUZIN. Even if you hadn't, the juxtaposition of those two elements, overutilization where it could be harmful to patients and make their lives miserable in the last days and overpricing that could possibly encourage it is a situation we should not tolerate; is that correct, sir?

Mr. GROB. That is right .

I think the reason we could say that was in that case we found representatives, nurses from the infusion company, that were screening the nursing home patients as they came into the nursing home. So there was actually a presence there. So it went beyond mere speculation——

Chairman TAUZIN. Again, my apologies to any physician who thinks I may have slammed them. My mother is a three-time cancer survivor. I pray at the altar of this medicine that has saved my mother's life. So don't get me wrong. I love any doctor that I know takes his oath seriously and practices it. I defend my own profession, the legal profession, against slams whenever they come unfairly, but I don't defend unscrupulous lawyers, and I will not defend an unscrupulous system that puts people into this position or

creates this image when it should not exist. So I hope that clarifies it a bit. The bottom line is we ought not create a system that even creates an image that anyone is providing infusion medical services to a patient in those kinds of conditions with any kind of connection to the fact that there is this availability of huge profits involved for doing it rather than the needs of that patient and the wonderful care and concern that almost every doctor I know provides to those patients, and I am talking about the fact that in every profession there could be a few bad apples and we ought not encourage them.

Thank you, sir.

Mr. GREENWOOD. I thank the gentleman, and the Chair recognizes for 5 minutes the gentlelady from California, Mrs. Capps.

Mrs. CAPPS. I have to acknowledge I am struggling a bit to figure out how to pose it. I have two different things I would like to talk about, but I am curious, Mr. Bentley, you gave kind of an autobiography in a way, if you will, of your company in the beginning with the treatments that you provided and then blowing the whistle, if you will, or noticing the discrepancies that you did, and I am curious to know—you were squeezed out of—you opted out of certain partnerships or relationships that were offered to you. What is the status of Ven-A-Care now?

Mr. BENTLEY. Right now we spend most of our time trying to educate and shine the light on what we feel that are abusive practices and abusive reimbursements so that we can hopefully have a level playing field some day and go back and do what we have always done.

Mrs. CAPPS. So you are actually in this business of doing these studies or looking into these discrepancies pretty much full time now.

Mr. BENTLEY. Pretty much full time, yes, ma'am.

Mrs. CAPPS. If I could turn to Mr. Scanlon and/or Mr. Grob, I am sort of anticipating the testimony of the next panel because you have been doing a number of studies that point out what we are all sort of flabbergasted to hear today, to have discovered. To me, and I know all too personally that it isn't coincidental that this is the field of oncology where we have regulating agencies' reimbursement standards that are being set for a field where, because of the investments that the Congress has made in the National Institutes of Health and other research arenas, cancer treatments that were clinical trials 5 years ago are standard today or even 2 years ago. That makes a challenge for a regulating agency to come up with pricing and all of the scheduling, and I would mention also that there have been some discussions about—that oncologists don't have any allowance within their offices for administering for the nursing care that goes into this as well and so some of the incentives for part of our problem come out of what I call the inability of our Medicare and Medicaid organizations to keep up with the changes, and I would like to have your comment on that.

Mr. SCANLON. There is no issue that it is a real challenge to keep something as complicated as a physician fee schedule up to date because we all know that medicine is changing for the better and we would not want to have any kind of system discouraged. At the same time I think the changes are sometimes not as dramatic as

they are portrayed and it is more of an evolution than a revolution, and we can keep data more current and keep our systems more in line.

Now, in this regard, in terms of the physician fee schedule, the Congress stipulated that specialties could provide information, current information, to allow CMS and previously HCFA to update the fee schedule, and some specialties have. The oncologists have not. There are standards for the submission of this information in that the information has to be representative of the profession, it has to be information that is collected from a large enough sample to provide a reasonable basis to proceed forward. That is part of this and I mentioned we were doing another study to see how information can be updated.

Another piece is the issue of how has the delivery of a service changed in terms of the nursing time, other staff time, supplies and other resources? That part needs to be continuously updated as well. There are some mechanisms in place. We will be looking at those to see how adequate they are.

But let me go back to another issue you raised, which is that certain costs are not being recognized within the system. All costs in the data that are available to CMS were recognized. There was the one adjustment in terms of supply expenses but all nursing costs that were in the data that were available were recognized. It is a system that does compensate for some weaknesses by recognizing these costs and then trying to allocate all of these costs across the different procedures. So we have some faith in the system. We have some concerns about how one keeps the data to operate the system as timely as one needs, and that is what we are studying at this point.

Mrs. CAPPS. Just one follow up if I have another minute. You are saying that the discipline of oncology, that those associations of doctors have not been forthcoming with data that you asked for?

Mr. SCANLON. In terms of information that we have asked for, they have provided some of that. In terms of information they could have provided to CMS to allow their fees to be recalculated, they have not done so.

Mr. BENTLEY. May I add to that question?

Mrs. CAPPS. Please.

Mr. BENTLEY. There is a drug that came off of patent, Taxol. It is a very important cancer drug. It has been on patent for approximately 5 years, originally derived from a California tree. So it is now being challenged by generic competition. So you would think the government would start saving some money because there is price competition, and this came across our fax, where this came across May 9, the first generic Taxol is introduced in the market, and they are already touting the spread, and the manufacturer came in with an AWP that was only slightly under Bristol-Myers Squibb's AWP; so the government is not benefiting nor are the patients nor Medicare or Medicaid from the fact that there is price competition occurring. And I question the fact that for 10 years Taxol was on patent and I don't think any oncologist was refusing to give Taxol to patients because there was no spread for those 10 years. When Bristol-Myers Squibb made a representation about the

price, that is what they sold it for. How did Bristol respond to the generic competition?

Here is the next, where you see that Bristol-Myers' Taxol, they lowered their real price in order to meet the competition but they didn't report a lower price to the reporting services, and yet again yesterday I got another fax that now then there is a second generic that has come onto the marketplace and the prices have dropped about another 20 percent in the last 48 hours but yet they put an AWP on their generic, exactly the same AWP that IVAX put on the first generic. So again Medicare and Medicaid and all the private insurers are not going to reap any benefit. And Taxol, the government currently spends, just Medicare, about $250 million a year on Taxol.

Mrs. CAPPS. It is now standard treatment for breast cancer.

Mr. BENTLEY. Correct.

Mr. GREENWOOD. The Chair thanks the gentlelady and recognize the gentleman from Iowa, Mr. Ganske, for 5 minutes for inquiry.

Mr. GANSKE. Thank you, Mr. Chairman. The area of oncology is kind of a special one as it relates to drug expenses because what one person may say is medically necessary, another person may say isn't. Let me give you a real life example. You have a patient with lung cancer, it spreads to his chest, lymph nodes and to his neck, not a very good prognosis. The oncologist tells that patient, you know, we could put you on chemotherapy, you have a 30 percent chance of responding, and if you do, it may extend your life 2 or 3 months. Now, is that medically necessary or not? And in addition you may not feel very good for some of that time. You know, one person may say I don't think that is—I don't want to do that and another person may say those 2 or 3 extra months with my family may mean a great deal to me that I think is necessary. That is how difficult it is to make some of these determinations.

That said, I think I want to thank this panel for being here; Mr. Bentley, you in particular for some of the data that you provided to us because I agree. I mean I agree with you, Mr. Grob, when you say the average wholesale price is a number that is misnamed. It is clear that we are not getting real numbers and so when you look at—I think this committee should look at the recommendations that you make. We co-authorize a commission to set payment rates. We could calculate a real rate. We could collect the invoices and do a real number if that is what we want to do. But I think there is a bigger question that this committee should look at, and that is do we want to continue in this way and what are the options? What are the options if the Federal Government is going to pay for these drugs? Well, we co-pay at cost. We could just pay what the invoice says. I mean does anyone want to do that? What are the controls on that? Then you can get any type of cost you want.

Okay. We could pay at any true average. That is where you have had it in terms of your recommendations. Well, what do you do about then a large purchaser who is able to get a discount off that true average vis-a-vis a smaller purchaser who doesn't have that kind of leverage?

And finally, you know, we could just set the prices and, quite frankly, I think if you chose the first option of paying at cost, that

is exactly what the Federal Government would do because that is what it has done on every other aspect of Medicare. So I think that whenever we are looking at simply paying at cost or coming to a true average, we need to think about this big picture here as well. My personal preference at this time is we need to reform this, we need to get the actual numbers and then somehow take into account the fact that you can't ask certain smaller purchasers to actually take a loss if they cannot achieve the average, and I am not sure exactly how we do that.

Mr. Bentley, do you have any comments?

Mr. BENTLEY. Well, I would like to say that the prices that we have provided to the committee we think represent those that are available to an extremely small provider. Ven-A-Care virtually has no buying power, and yet there are much better prices for large purchasers and so what we are showing you is just the disparity that is occurring between the reimbursement prices and what a very small provider is very able to acquire these drugs for.

Mr. GANSKE. So do we throw out the AWP or actually make it into a real AWP?

Mr. BENTLEY. There are a lot of drug companies that think AWP really means something and when they make a representation about their average wholesale price that is effectively what it is.

Mr. GANSKE. So for those who are playing the game honestly, it shouldn't affect them that much?

Mr. BENTLEY. That is correct. And in fact I don't think you have physicians that are saying we are not going to prescribe or dispense Lilly drugs or Merck drugs because there is no financial incentive or inducement for us to provide those drugs. I am not aware of any evidence of that.

Mr. GANSKE. Mr. Scanlon, have you looked over the IG's recommendations? Do you have any preference in terms of this list of ways we could go?

Mr. SCANLON. I think taking into account market prices, which is to recognize the average price being sold, is important. Whether it needs to be at the average or somewhat above, to recognize that there may be small purchasers who cannot obtain the average is the key. And we think that the data that CMS has available would allow us to look at that. We did look at small physician purchasers in terms of prices they could get and we did a survey of them and among the ones that responded and gave us prices, they all could get prices that were as good as the discounts that were reported, which are catalogue prices, and these catalogues are something that any physician can buy from.

We talked about it as a starting point and the Inspector General has talked about it. If you are willing to use the catalogue and pay that price, you will get it. If you negotiate, if you can deliver some volume, you may get a much better price. I don't think we are in a position where we want to begrudge the providers that get better prices and say we have to find a way to get it down to the absolute minimum. We are more concerned about the system that is out of control at the other end—the price that is being paid by Medicare—which is so far and above the price that is actually being paid by even the provider getting it at the highest price.

Mr. GANSKE. Thank you, and thank you, Mr. Chairman.

Mr. GREENWOOD. I thank the gentleman and recognize Mr. Burr for inquiry.

Mr. BURR. Mr. Scanlon, is this something that we have just realized for the first time that Medicare pays too much for prescription drugs?

Mr. SCANLON. As Mr. Grob indicated, the Inspector General has been looking at this for a long time and the conclusion has been the same.

Mr. BURR. Why haven't we fixed it?

Mr. GROB. We started it in the mid-eighties but we intensified our work a few years ago, in 1997, and we have issued updated studies every year since then.

Mr. BURR. Why haven't we fixed it?

Mr. GROB. I can't hear your question. I am sorry.

Mr. BURR. Why have we not fixed it?

Mr. GROB. There have been impediments, including a legislative impediment.

Mr. BURR. It would actually require a legislative fix?

Mr. GROB. I believe that would be better——

Mr. BURR. Could HCFA have made changes in the past?

Mr. GROB. CMS could have used its inherent reasonableness authority to do so. It could have obtained better data and made it available. It has tried to do that.

Mr. BURR. Have you ever looked at any other area of Medicare reimbursements and found that people game the system?

Mr. GROB. Yes.

Mr. BURR. All areas? Some areas?

Mr. GROB. Very many areas.

Mr. BURR. As a matter of fact, we reacted to a number of them when we did BBA 1997——

Mr. GROB. Exactly.

Mr. BURR. Did we get them all right?

Mr. GROB. We made a lot of them better.

Mr. BURR. But we got some wrong?

Mr. GROB. I don't know which ones you have in mind.

Mr. BURR. Because in essence we try, like HCFA did, to calculate what a proper reimbursement is based upon the delivery of a product and that delivery can change based upon geographically where you are in the country, what the rental rate is. There are a lot of factors that come into play?

Mr. GROB. Exactly.

Mr. BURR. You from the standpoint of the Inspector General's office have come up with nine suggestions as to how we fix it. I will attempt to refocus everybody here on the solution because I think that everybody here is in agreement that we have a problem.

Mr. GROB. Yes.

Mr. BURR. That the average wholesale price is flawed, that we have lived with it for way too long, that we have not shown the backbone within the agencies that have jurisdiction over it that could have done it or within the halls of Congress where we could have legislatively fixed it. For whatever reason let us put that behind us and all agree it is wrong. You have come up with nine suggestions. Are there any of those that you would highlight more than the others?

Mr. GROB. Yes. I like the idea of the commission, and that is why I put it first. Another one I think would be good would be to use the manufacturer's price that is used in connection with the Medicaid rebates as a source of data. I think it might be more helpful if I could give a few general principles that——

Mr. BURR. Go right ahead.

Mr. GROB. I would agree that I don't think we need to have the bottom amount. I think, as several have mentioned, there is room for some play here. I don't think we should base it on cost. What we have done basically with Medicare is move completely away from that. Hospital payments were based on cost and we had double digit inflation. And then there was Medicare physician payments, and we had very high inflation; so we went to a fee schedule. We have just gone to a fee schedule in the form of prospective payments for nursing homes, home health, and other types of facilities such as outpatient hospital costs. We have learned our lesson. If you go on cost, the actual cost an individual has occurred, you immediately come across two problems. One is looking over everyone's shoulder as they write every check wondering exactly what it is. And you can never keep up with it. And then if you actually could succeed, then no one would care what their costs were because they would get reimbursed for them, and that would drive the prices up.

So cost based reimbursement has been the bane of Medicare since its existence and we have gradually corrected it in almost every area. So I wouldn't base it on the actual cost the person has incurred. I would substitute some kind of a Medicare payment rate which I think has to take into account primarily what the market is. We have to have some sense of what is going on out there in the market. That could be obtained from something like the actual manufacturer's price that, the data that is submitted for the Medicaid program.

Those dollars are available. They can be audited. They need a little definition. You could do some market surveys, and I think that periodically, once a year or so, maybe more frequently, there can be a price set, and then that is the price. I would agree with what you are saying here. I don't think we look over a doctor's office and say you can never make a penny on every piece of gauze in your office. We know there is some give and take. I think people just don't want it to be very big or be a source of gaming and incentivizing.

Those are some general principles. And out of that you could choose one or more of those options, none of which would be perfect, but they all would be better than what we have.

Mr. BURR. Let me mention—Mr. Scanlon can comment on it and also Mr. Bentley—these highlighted solutions to fix an AWP.

Mr. SCANLON. I concur with Mr. Grob, relying on the market. This is one of the few instances where Medicare may be able to rely on the market and what other purchasers are doing. Normally Medicare is such a dominant purchaser that to say we are going to pay what other purchasers pay would distort the market. But in the case of prescription drugs right now Medicare is paying for a very small share of them and they are easily defined commodities. So you are able to specify what you are getting and you are able

to look to other purchasers and what their experience is. CMS has access to the information it needs. It doesn't just need an average price. It needs to know the circumstances under which buyers are getting different prices to be able to set a fee that is going to be adequate so that purchasers in different circumstances are able to buy drugs and supply them to Medicare patients.

So using that information, which is market driven and therefore I think a reflection of the efficiencies of what a market can produce, is key here to setting market prices on a more rational basis.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes——

Mr. BENTLEY. Could I just comment briefly?

Mr. GREENWOOD. Yes, sir.

Mr. BENTLEY. I would like to add that the hallmark of any change in reimbursement system has got to be some truth and honesty from the drug manufacturers because without that any system you go to is going to be doomed to fail, and I point to a number of Medicaid programs who do not use representations of AWP to formulate reimbursement decisions. They use wholesaler acquisition costs. California for 12 companies uses manufacturers' direct prices. There is also cases where in some States they are actually using invoices that are submitted by providers. So if you have manufacturers who are willing to make false statements about the wholesaler acquisition cost, about the direct prices they are selling it to, trumping up invoices so that provider submits an invoice for a thousand dollars when in 30 days they receive $500 worth of free goods and so they really paid $500, any system is doomed.

Mr. BURR. Clearly I think the panel would agree, and I appreciate the Chair's indulgence, that we have the tools available to us to fix the average wholesale price. The question is do we have the willingness to fix the average wholesale price? No matter what we choose, whether it is option one or nine, we will still be susceptible to people who find a way to game the system; correct?

Mr. BENTLEY. Absolutely.

Mr. BURR. We will still need an Inspector General to help us on that.

Mr. BENTLEY. There has to be consequences for those who choose to break the law.

Mr. BURR. We can do better than what we have. I thank the Chair.

Mr. GREENWOOD. The Chair thanks and recognizes Mr. Stearns.

Mr. STEARNS. Thank you, Mr. Chairman. I want to lead off with the comment that Mr. Burr mentioned that there has to be consequences. I wonder if the staff could put up on the screen document number F-2, which is dealing with Bayer Pharmaceutical Division. Let me say while we are trying to find it that this is an internal company e-mail that states—in talking about their competition, it is a an e-mail that says, "Chris, if Baxter has increased their AWP, then we must do the same. Many of the whole care companies are paid based upon a discount from AWP. If we are lower than Baxter, then the return will be lower to the HHC. It is a very simple process to increase our AWP and can be done overnight. Let us talk about this at our meeting at Old Saybrook."

So there we have it pretty clear that Bayer Pharmaceutical Division in this case is working to increase the AWP not based upon scientific evidence but based simply upon trying to work out that they get paid more, they give the medical providers incentives, and of course it works out that the wholesaler gets paid more too. So everybody makes it and this continues to go forward.

Let me ask the staff to put document number 7. This is a document from Baxter. I just read one from Bayer and now I would like to read one from Baxter, where they are talking about the AWP and they are saying "This price is being promoted by certain manufacturers' sales forces as a financial incentive to use their product."

So here again we have Baxter Pharmaceutical as saying we have got to get on board here because people are using this as a financial incentive to use their product. They go on to say, "The deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition costs and AWP/WAC is a direct profit for customers and is being used to increase product positioning in the market by certain manufacturers."

So I thank the staff for these documents and I obviously thank the staff for what they are doing here and you, Mr. Chairman, and the chairman from Florida, Mr. Bilirakis. But on a larger note, Mr. Burr touched upon the idea of what can be done. One of the things that can be done is to have the Justice Department enforce under the antitrust rules what has been accomplished simply in this memo.

Now, this was not a big, big problem at Medicare until the nineties, but this has been going on for almost a decade. So in a larger sense Medicare, HCFA, has been a little bit asleep at the wheel because they don't necessarily—I mean I don't think you can blame Congress totally here because they could have done something like Medicaid is doing. Medicaid did something on their own to establish a new AWP system where the rebates will be based upon a more accurate model.

So I think, you know, when you come to these hearings, and I have been to a lot of them and it is almost numbing to see these things, there is a lot of blame to go around, but I don't think Congress is totally at fault. I think HCFA should have done something about this in the early nineties, and obviously I think the Justice Department should have taken examples where Baxter and these other pharmaceutical companies were in collusion in trying to raise AWP without any reason other than to increase the spread for their medical providers to give them incentives.

So I am always a little bit nonplused to sit here and we talk and talk and I say where is there someone that is going to take some action on this.

Another question I have for you, Mr. Grob, you mentioned that we could save as much as a billion dollars a year if we stopped this.

Mr. GROB. I believe at least a billion.

Mr. STEARNS. That goes to a larger question that President Bush has mentioned that he wants to reform Medicare to give pharmaceutical help to those who are poor who need this. So here the government is squandering a billion dollars a year and this could be going to beneficiaries who can't afford pharmaceutical drugs. So this is an area where this whole package of reform is what Presi-

dent Bush has talked about in the campaign and in the presidency. With a simple quick decision by HCFA to move to the Medicaid position on this, wouldn't that solve it immediately?

Mr. GROB. The Medicaid program is complicated and has two features to it.

Mr. STEARNS. One of your recommendations—but instead of Congress sitting here and debating this thing, we go through the subcommittee and the full committee and the House, what can HCFA do tomorrow to make this so that we stop this?

Mr. GROB. CMS would have its options limited to obtaining the most accurate market data it can find and making it available to the carriers in setting their prices and reducing them.

Mr. STEARNS. Well, couldn't they say every pharmaceutical has to give us your wholesale price, certify it, and if it is incorrect, you will go to jail? Is that——

Mr. GROB. We basically have almost the equivalent of that in the Medicaid program, which is why I brought that up. Because of the rebate program the manufacturers are in fact required to submit that data, the manufacturing price we will call it, to the government, and that data is available. Now, if there were legislative authority to use it, that would probably be the quickest fix.

Mr. STEARNS. Okay. Mr. Scanlon, anything you would suggest?

Mr. SCANLON. We believe very strongly that using the data that is available through the Medicaid rebate program would be the quickest vehicle in terms of trying to improve this pricing because it is data that details what manufacturers are selling drugs for under different circumstances. There are statutory requirements here and Medicare under the Balanced Budget Act must pay 95 percent of average wholesale prices. Whether that has to be this fictional price in terms of what is reported in the Red Book for some manufacturers or whether it can be actual average wholesale prices is another issue, and that is where I think reasonableness authority would be something that the agency could do.

Mr. STEARNS. I want to conclude my statement, if I can have additional 30 seconds in my conclusion here, Mr. Chairman.

Mr. GREENWOOD. Without objection.

Mr. STEARNS. Mr. Bentley sent to Dr. Bruce Vladek a memo on June 12, 1997, in which he outlined all of this, and I would say, Mr. Bentley, there has got to be a place for you in the pearly gates up there and if you have any trouble after this hearing call us because we are with you 100 percent and appreciate what you have done. But I would say to the former Administrator what we have here from Bentley's memo here, which is part of the records I believe, shows that we have a scandal like we had with the $400 toilet seats in the military, we have the equivalent of that here in HCFA, and I think Mr. Bentley actually showed this photograph to the head of HCFA back in 1997, saying, look, your legacy is going to be the $400 toilet seat, that this is going to apply to this whole problem dealing with AWP.

Thank you, Mr. Chairman.

Mr. GREENWOOD. Thank you, Mr. Stearns. Each of the members has had an opportunity to ask—except for Mr. Green from Texas, who joins us now and is recognized for 5 minutes to inquire.

Mr. GREEN. Thank you, Mr. Chairman, and I appreciate the appearance of our witnesses simply because those of us who are moving in and out and representing Intercontinental Airport in Houston with Continental Airlines, obviously we have a much bigger issue, but I am glad this postponed hearing is taking place, and the issue I think is so important because of the criteria that, Mr. Grob, you talked about in your testimony, and in your testimony you referenced the considerable savings that the Medicare program can recognize if they utilize Federal Supply Schedule as the basis for prescription drug benefits or reimbursements. A number of us in Congress have been advocating this approach for years, not only for the few prescription drugs we provide for under Medicare but for prescription drugs for seniors as a whole.

Now I know in this issue seniors may pay more for their 20 percent co-pay based on this pricing aberration, but generally overall would you say that the high cost by using the Federal Supply Schedule would benefit not only the issue we are here today about but also seniors in general who may not have a prescription plan as part of Medicare?

Mr. GROB. On the surface it would certainly seem to provide a lower cost for the beneficiaries. But I would really have to say that that really is beyond the scope of other studies that were done because there would be other ramifications concerning the market, and so I would say on the surface it would have that effect, but what the other effects are we haven't studied.

Mr. GREEN. I understand. I was looking at your statement. Again I think we have made that issue here in the committee a number of times and just by using the Federal Supply Schedule we cannot only save the Federal Government maybe a billion dollars under Medicare but how many billions do you think we can save the average senior citizen who——

Mr. GROB. If you were to use the Federal Supply Schedule amounts for the drugs that we looked at, you would save almost $400 million a year for the beneficiaries.

Mr. GREEN. That is just on the oncology——

Mr. GROB. No. We looked at 24 drugs and I think it was about $350 million or more of savings for the co-payment for Medicare beneficiaries for the 24 top selling drugs in Medicare, top drugs. That included inhalation drugs.

Mr. GREEN. That is for the co-payment for those 24 drugs?

Mr. GROB. Exactly.

Mr. GREEN. I know neither of us can extrapolate too well but if we would provide that to the gamut of pharmaceuticals that seniors have to pay that is not subject to a co-pay, they just—if they are under regular Medicare, they go down and buy their prescription from their doctor, and the Federal Supply Schedule is much less than what I may go down to buy at my pharmacist or my sister or mother or father may do.

Mr. GROB. Exactly.

Mr. GREEN. Mr. Scanlon, you admit in your testimony that the oncologists are often underpaid by as much as 15 percent, and you stated that if we modified the practice expense payments on college practices it could increase their reimbursement by 8 percent, or $31 million. You also reference a modification of the formula used to

calculate supply expenses, which would increase oncology practice expenses by about $20 million. I understand that the Medicare statute requires that any changes to the practice expenses for one specialty be budget neutral, therefore if we increase oncology payments we would have to cut payments from another specialty, and I guess that is—I know I followed my chairman a little bit. If we are going to save maybe upwards to a billion dollars in Medicare and we should reimburse oncologists 15 percent, can that come out of savings or are we going to have to take it from cardiologists or other reimbursements?

Mr. SCANLON. It is your decision whether or not you want to add to the pool of dollars that are being paid physicians and whether it is going to come out of the savings. One of the important things to remember here is that the budget neutrality principle was applied at the very beginning, so therefore when the oncology fees were calculated, and they are $51 million less than what they would have been if a different method would have been used, and that $51 million was then spent on other specialty services. And some of that $51 million was also earned by oncologists because some of their physician services had higher fees associated with it, and the $51 million in terms of the overall physician fee schedule is about two-tenths of 1 percent. So we are talking about a redistribution of a very small amount of money.

Mr. GREEN. But your testimony is we wouldn't necessarily by increasing oncology have to decrease other specialties?

Mr. SCANLON. No.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. GREENWOOD. Each of the members has had a round of questioning. There are a couple more points that need to be made. So we are going to go through a second round for those who want to. It is not mandatory.

The Chair recognizes himself for 5 minutes and would ask the staff to bring up chart P-1. I want to go to the question of utilization because we have talked about the way in which savings could rendered to the Medicare program and overpayments were made just based on normal levels of utilization, but I want to look at ways in which the spread and the false AWP payments can affect utilization, and let us look at this product here, which is ipatropium bromide, which I believe is a therapy for emphysema, and similar pulmonary diseases.

In 1995, when there was no spread on the drug, Medicare paid a little more than $14 million in that year. As you can see, as each year passes and the spread becomes larger, utilization skyrockets. Today, 6 years later, Medicare pays more than $347 million, over a third of a billion dollars, for this drug alone.

Mr. Bentley, I am going to ask you if you could further illuminate this issue.

Mr. BENTLEY. Yes, sir. This is an interesting drug because prior to 1995 it was a patented drug with no generic competition and here again, like the Taxol example, once generics came into the marketplace the prices started dropping precipitously; that is, the prices to the providers. However, the government, both Medicare and Medicaid, has not achieved any savings due to price competition and in all likelihood it is kind of a double whammy because

we believe a lot of this utilization is directly attributable to the spread.

A case in point, recently Texas, their Medicaid program, based on some information Ven-A-Care provided for another inhalation drug, albuterol sulphate, where there was a rather large spread——

Mr. GREENWOOD. Perhaps the staff can bring up document P-2.

Mr. BENTLEY. [continuing] cut its Medicaid reimbursement in Texas. Now, they were cutting their reimbursement, so that would affect access to care. I can tell you this. They reduced the prices dramatically that they reimburse under the Texas Medicaid program to the real prices in the marketplace. They have not experienced any access to care issues, and I heard yesterday from an Assistant Attorney General in Texas that not only are they achieving the savings by the reduction in the prices, they have also started achieving about a 20 percent reduction in the utilization.

Mr. GREENWOOD. Mr. Scanlon and Mr. Grob, do you care to offer any comments in this regard?

Mr. GROB. We have done additional work on nebulizer drugs, looking at the utilization of those, and based on 1994 data we found about $30 million of the nebulizer drugs that were used were drugs that should never be used in combination. We also found instances of amounts that differed from prescriptions. We also had amounts that varied from the Medicare guidelines for these drugs. So we did find improper utilization and inappropriate utilization of these nebulizer drugs when we looked at them. This is primarily albuterol.

Mr. SCANLON. Mr. Chairman, we haven't studied this beyond the issue of pricing, and the pricing gap is the same that we observed, and I would note this is the kind of disturbing pattern that we have been talking about, increased utilization as the spread increases, and I would also note that there is some very aggressive advertising of these inhalation drugs.

Mr. GREENWOOD. Your study, the GAO study that showed roughly built-in savings that we could achieve only assumed the same utilization and it did not, as I understand it, acknowledge savings from more of a dynamic scoring, if you will, that would occur if the spread was not in fact driving utilization. So when given these two charts where we have seen how change in the spread dramatically affects utilization, would it be fair to assume that a billion dollars is a conservative number because without the incentives driven by the spread we would probably see a change in utilization? Is that a fair statement?

Mr. SCANLON. I believe that is a fair statement. We hope it would be a change in utilization driven by overutilization declining as opposed to genuine access changes as well.

Mr. GREENWOOD. The Chair yields back the back his time and yields 5 minutes to the gentleman from Florida, Mr. Deutsch.

Mr. DEUTSCH. You have a very insightful panel in so many ways, and hopefully it is our commitment to follow up on this. I want to focus on something we have talked about a little bit, and that is what can HCFA do and Medicare do without legislative action? The GAO issue today was in response to a Congressional mandate to do a comprehensive report on drug pricing before the Centers of

Medicare and Medicaid Services be allowed to change the payment structure for Medicaid drugs. Now that the study has been done and we have shown that the average wholesale price is flawed, it would seem as if the CMS should be able to go forward and use the catalogue pricing data obtained by the Justice Department as the basis for drug disbursement. Would you agree with that? Is that possible at this point in time?

Mr. SCANLON. I think it's preferable to use the information that's available through the Medicaid rebate program, in combination with the wholesale catalog discount——

Mr. DEUTSCH. Right. I guess the question, though, specifically is, can they do it now without legislative action?

Mr. SCANLON. They can do it without legislative action. As Mr. Grob indicated earlier, they would do it through the inherent reasonableness process, which is more cumbersome and over the years has resulted in very few changes in prices.

Now, you did give them expedited authority in the Balanced Budget Act to make modest reductions on an annual basis of 15 percent in prices. So that would be immediately accessible.

But we're talking about bigger changes here for a number of drugs, and that would take the more elaborate process. Obviously, if you provide them further statutory authority, it's going to expedite things even more.

Mr. DEUTSCH. Right. I guess I would just follow up, though. I mean, knowing the legislative process as well as you do, it's—you know, one of the reasons we delegate issues like this is administratively it's just a lot easier, especially, you know, in hearings like this when we're clear of what the situation is in the world.

Mr. Grob, did you want to respond?

Mr. GROB. I would hope that you would consider legislative action. Our experience has been that for the use of the inherent reasonableness approach that, actually, that has not been a lot easier than the legislative process. For some of the reductions that have been made, for example, for Oxygen, an initial attempt was made to use the inherent reasonableness, but it ended up getting made by the Congress, and that was done pretty effectively and fairly timely. Your point is that every means should be used and to the extent that there are administrative means those should be used right away. But I think the system is so flawed that we need a brand new system.

Mr. DEUTSCH. Well, let me throw it back. As far as you're aware in either HCFA or in HHS directly, I mean, is this something that the policymaker level—has this been presented to policymakers as an option for them to implement these changes administratively?

Mr. GROB. Okay. Sir——

Mr. DEUTSCH. What is the official, you know, sort of response to that?

Mr. GROB. Well, you'll have to follow up with Mr. Scully on this administration, but certainly our reports have been public and have always been written to the administrator of HCFA, now CMS. So they've always been in the mill, and there have, in fact, been, as I've said, some legislative proposals from the prior administration. So I think it's been on the table.

I think the value of this hearing is the dramatizing and the clarification. I think the subject takes intense study, and the work that went into this hearing has provided that, so that the insights are a lot clearer to more people now.

Mr. BENTLEY. If I could add, I believe the problem could be remedied tomorrow if the drug companies that are the culprits who are reporting these false prices contacted first Data bank and Red Book and submitted new prices, honest prices. And I point to the fact that approximately 90 days ago Abbott laboratories did that for Medicaid purposes, and there were a number of very important drugs where they made representations—I'll point to Vancomycin, one gram as an example—where they were representing the average wholesale price of being around $56 per gram. They were really selling it for less than $10.

Now, then, for Medicaid purposes, they initiated a new pricing to, First Databank where they repriced some 200 or 300 drugs with fairly honest representations. The State Medicaid programs across the United States started generating the savings immediately from Abbott's representations and from their actions.

So all we need is for these companies—maybe the hearing will be the impetus for them to have a change of heart and report new prices. CMS doesn't have to do anything. Congress doesn't have to do anything.

Mr. DEUTSCH. Let me follow up. Mr. Grob, what about that as a solution administratively? Could you or through—actually through—could HCFA change the definition of the average wholesale price and then just define it in a different way to—in such a way that would basically be the average wholesale price, for that matter?

Mr. GROB. I think the law says "average wholesale price," and I don't even believe that that phrase uses capital letters. I think the people who voted for that law, everyone who cast a vote for that law, probably thought it meant the "average wholesale price." So certainly CMS would have it in its authority to define that "average wholesale price" to mean what the English phrase means. And I think then if they could get the data to back that up, use data that's available, then in fact it could be done. And I do agree with what's been said here by Mr. Bentley about the publication of the data.

Now, these companies have had that option for many years. So I hope they do—I hope they do do it very soon.

Mr. GREENWOOD. The Chair thanks the gentleman from Florida. Mr. Tauzin.

Chairman TAUZIN. Thank you very much, Mr. Chairman.

Let me mention a solution that didn't work, so we don't do that one again, the Balanced Budget Act. We said we'd reimburse the average wholesale price minus 5 percent, and we all went, we'll be danged; we saved a lot of money. And the average wholesale price jumped 10 percent the next year. We didn't only not save money; we lost money. That was a non-solution.

A number of members have talked about the effect of this system on the Medicaid programs of America. In the Medicare program, we're talking about drugs generally that are used in three areas, right, and chemotherapy oncology-type drugs, inhalants and some

other specialties like urology. In the Medicaid system, it's wide open, isn't it?

Mr. GROB. Yes.

Chairman TAUZIN. We're talking about all drugs.

Mr. GROB. That's correct.

Chairman TAUZIN. In fact, Mr. Bentley, you brought a chart for a number of my colleague a few months ago. It's document S-2. I'd like to put it up. It's involving the drug Cefadroxil. And I want to look at the Louisiana Medicaid effect. This Cefadroxil—the chart indicates what the spread looks like on this drug in Louisiana, Pennsylvania, Florida, Michigan, Texas and Ohio. Texas and Ohio have apparently done a lot of work, yet the spread is down. They've got the spread, the difference that the State Medicaid program is paying out as opposed to the real price of the drug.

Mr. BENTLEY. Yes, sir.

Chairman TAUZIN. They've got it down to $16 and $35. But in Louisiana the spread on this drug, which costs Medicare $82, because of a Medicaid reimbursement of $274.50, is $191. The spread, the extra money made by the system to the provider, is more than twice as high as the—the spread, the additional profit, is more than twice as high as the cost to Ven-A-Care. Is that correct?

Mr. BENTLEY. Yes, sir.

Chairman TAUZIN. Let me turn to—anybody have any idea what this system is costing the Medicaid systems of America?

Mr. GROB. Yes. They spend about $16 billion a year, and the last time we studied it recently looking at the brand name drugs, we calculated a loss of about a billion dollars for the brand names. Now, we're working on the generic drugs right now, hoping to have a report——

Chairman TAUZIN. So we're talking not just about the billion in savings to Medicare. We're talking about billions in cost to the Medicaid systems of America——

Mr. GROB. Exactly.

Chairman TAUZIN [continuing]. Which is trying to provide medicine for the poorest of our Nation.

Mr. GROB. Exactly.

Mr. GREENWOOD. Would the gentleman yield for a second?

Chairman TAUZIN. Yes, I'll be glad to yield.

Mr. GREENWOOD. So, on average, since the Federal Government pays 50 percent of the cost of Medicaid drugs, would you argue that, if we changed the system, that there's a potential to save minimally now a billion and a half dollars to the Federal Government. Is that a fair statement?

Mr. GROB. I'm sorry. I didn't quite follow.

Mr. GREENWOOD. Given that the Federal Government is paying—reimbursing the State Medicaid programs for, on average, 50 percent of the price, if they're squandering at least a billion dollars additional——

Chairman TAUZIN. The chairman is making the point that any dollars we save to the Medicaid system, 50 percent is a Federal saving. Right?

Mr. GROB. I'm not sure whether the billion is the total of Federal and State or only the Federal part.

Chairman TAUZIN. And it may be much more than a billion.

Mr. GROB. As I said, we've only done the brand names——

Chairman TAUZIN. Let us look at examples of excessive reimbursements with pharmaceuticals by the Louisiana Medicaid Pharmacy Program, one I'm very interested in. If we can put—that chart is up now. And we can look at one drug—Elkins-Sinn's drug called Leucovorin again. The lowest price according to this report, Mr. Bentley, that you've seen in the marketplace, the real price, is $2.39.

Mr. BENTLEY. We actually prepared this chart a couple of years ago, and that is why there is the discrepancy between the Leucovorin here of $2.30 and I believe our other chart where it was $1.25. Leucovorin has actually gone down in price, yes, sir.

Chairman TAUZIN. But the average Medicare price is $21.70. The Louisiana Medicaid reimbursement is $50.34.

Mr. BENTLEY. Twice what Medicare was——

Chairman TAUZIN. Twice what Medicare is reimbursing. And, what, 30 times the price of the drug in the marketplace today or more? That's amazing.

And you go down the list. I mean, you see another one that stands out again, Vancomycin, a price then of 3.45. I don't know what it is today. Medicare was reimbursing it at $9.44. Louisiana reimburses at $30.43. How on earth are we going to keep our Medicare programs alive if they're being drained at that kind of rate?

Mr. BENTLEY. That's correct.

Chairman TAUZIN. In fact, I've got a quote from the Wall Street Journal about the program in Missouri where they're saying they've got the biggest core cuts in their Medicaid program in history, and it's going to affect the amount they can spend on education and other vital State needs because it's driving the cost of the Medicaid system into near bankruptcy.

Mr. GANSKE. Would the gentleman yield?

Chairman TAUZIN. I'll be glad to yield to my friend.

Mr. GANSKE. Well, Mr. Chairman, we've all in the past been rather amazed at how cagey those Cajuns down there in Louisiana are on the Medicaid program, but I wondered if we could——

Chairman TAUZIN. Well, I don't believe I want to yield to the gentleman if he's going to insult my Cajun but——

Mr. GANSKE. I want to tie this, though, to the point that Mr. Grob made in No. 2, in how, Mr. Grob, you suggested that maybe we ought to look at—in fixing AWP, we ought to look at what Medicaid has done.

Chairman TAUZIN. That's part of my point. That's the last place we ought to go for advice is what I'm trying to point out.

Mr. GANSKE. Well, maybe that's not the case, because maybe Louisiana is an exception over what has gone on with AWP.

Mr. GROB. Can I make an important distinction?

Chairman TAUZIN. Yes, please do.

Mr. GROB. The Medicaid program achieves savings in two different ways. One of them is that they get discounts off of AWP the same way Medicare does, except they generally get more generous discounts. Now, that's not what I was talking about. There's another part about Medicaid, which is the rebate program, where the manufacturers must return money to the Medicaid in light of the expenditures made, and that is the part I was talking about.

Chairman TAUZIN. That can be instructive. I agree with that. But the point I'm making is that the Medicaid reimbursement is still worse than the Medicare. That's the last place you want to go for advice on how to set an average wholesale price for the Medicare program.

And I want to point out something else, too, and that is that if we're going to correct this the obvious place to look for the real numbers is in the real marketplace with the numbers, Mr. Bentley, you provide for us—you've been providing for us as to what Ven-A-Care can really buy these drugs for. I mean, we're talking about reimbursing two categories of services: one, the service, the practice; and the other, the drugs that are used. In both cases we ought to look at the real marketplace, what is the private sector costing these two systems. And the government ought to reimburse close to those numbers.

If we don't—if we are reimbursing $50 for a drug that costs a dollar and a quarter, you were telling me, Mr. Bentley, what are we, just insane? And are we going to drive these programs to the point where they can't provide the services they were intended to provide for citizens of this country? We entitle this effort. I want you all to know it.

I think Mr. Burr came up with the title to this whole effort we're trying to undertake in reforming Medicare and this whole pricing system and getting more drug coverage for more Americans. We called it Patients First. Patients are last in this program. They're getting killed.

Mr. SCANLON. Mr. Chairman, I just wanted to note that what we are talking about here is trying to use private sector transactions and information to try and set Medicare prices on a more rational basis. The Medicaid program at the Federal level has the requirement that manufacturers turn over to CMS information on private transactions with genuine net prices, not the types of catalog prices that we've been talking about——

Chairman TAUZIN. Well, tell me about Texas. Texas has been trying to do that, hasn't it? Mr. Bentley, aren't you involved in that? Aren't you involved somehow, and isn't Texas going through hellacious problems? And they're probably leading the country in trying to get this straightened out.

Mr. BENTLEY. That's correct. Texas does not rely on prices that are submitted to either of the publication services, Red Book or First Data bank. They actually go to a certification form, and that's sent directly to the manufacturer.

Chairman TAUZIN. They're ahead of the rest of the States, and they're having a heck of time, aren't they?

Mr. BENTLEY. That's correct. And also, unfortunately, when a manufacturer makes false representations about their prices, the Federal rebate program is not making the States whole for the difference. So they are not—the Congressional intent, as I have read it, of OBRA 1990, which was the State Medicaid rebate program, was to give the State Medicaid programs the benefit of the manufacturers' best prices. But if you start out with false prices, even though they're giving a rebate back to the States, the States are not anywhere close to being at the manufacturers——

Chairman TAUZIN. They're taking a lot more than they're giving back. Is that right?

Mr. BENTLEY. That's correct. Yes, sir.

Mr. GROB. One last clarification. What I was referring to in using the Medicaid program is that there is a very rich source of data that the manufacturers must submit to CMS, not to the States, which is their actual manufacturers' prices, taking into account the discounts that have been offered that are maintained confidentially by CMS but that are used by them. That source of data, which is auditable, is already available. It's submitted every year, and it reflects the actual prices that the manufacturers are charging for the retail sale of drugs. All I was saying is that that data could be used as a basis——

Chairman TAUZIN. I agree with you. I'm not arguing that. I think you're correct. I think there's a good wealth of data there.

My time is up. I just want to make the point again, everything we do to correct this problem—and I love the way Mr. Burr focused on that, on the different solutions you come up with, because that's really what we've got to get to. In every way we correct that problem, we're not only going to save the Medicare program this billion dollars; we're going to save the Medicaid programs of the States possibly their life, their function, their capacity to do their job. And 50 percent of those savings will be inured back to the Federal Government, because we have a 50 percent responsibility in those State programs. I mean, this is very well worth doing, and you're helping us, I think, see our way to it.

Thank you very much.

Mr. GREENWOOD. The time of gentleman has expired.

Does the gentleman from New Jersey, Mr. Pallone, seek recognition? The gentleman is recognized for 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman.

I wanted to ask Mr. Bentley to comment on some documents. I have a series of documents that were obtained by the committee from Glaxo that detail at least part of their marketing strategy around the Zofran market. And we have those. Okay. I'd like to read, Mr. Bentley, parts of several documents and ask for your comments and ask, Mr. Chairman, that the documents in their entirety be placed into the record if they haven't been already.

Mr. GREENWOOD. I believe they have been, but without objection, they certainly will be.

Mr. PALLONE. Thank you.

The first is a memo dated January 31, 1994 in which this—do we have it up there, or should I wait a minute? Oh, it isn't part of that. Okay. All right then. I'm going to have to read this, Mr. Chairman.

The first is a memo dated January 31, 1994, in which this bullet point appears: Telemarketers who could sell the reimbursement issues with Zofran: Example, because of the contract price on Zofran, there is almost a 20 percent spread between doctors' acquisition costs and AWP. With the price of Zofran being most likely higher than Kytril, it will be to the physicians' best interest to continue to use Zofran.

As you can see, Zofran will mean more profit for the physician. Oncologists seem to be more business-oriented than most physicians. This will be an excellent selling point.

Did you want to comment on that?

Mr. BENTLEY. That's correct. Unfortunately, a lot of manufacturers' representatives are going out and marketing their respective drugs not based on the efficacy of the drug but what in fact will put the most money in either the physician's pocket or the pharmacy's pocket, and so you have a case where there's marketing actually going on to encourage the utilization of one drug over a competing drug by using government funds that fund the kickback as a marketing mechanism.

Mr. PALLONE. And how common is this kind of telemarketing?

Mr. BENTLEY. It is very common.

Mr. PALLONE. Okay. Well, the second——

Mr. BENTLEY. Especially with the drugs that are at the focus of this committee's interest. I guarantee you that their sales representatives are out pounding their beats every time they've raised an AWP or they've lowered a price. Just like those Taxol examples, they get faxes out immediately, followed by telephone calls that, hey, our price has gone down in the market. Buy my drug over my competitor's drug.

Mr. PALLONE. Okay. Thank you.

And then, Mr. Bentley, another of these documents dated October 15, 1997, was developed in anticipation that a third drug, Anzemet, will enter this market. And if I could read a section there for you to comment on.

It says, the package insert includes a warning concerning cardiovascular side effects and describes one episode of complete heart block and one death. A bolded precaution supports the warning.

Now, you're familiar with the actual competition in the marketplace between these three drugs that I've mentioned. Would you say that side effects such as the apparent FDA concern about Anzemet play a prominent role in physician choice of drugs?

Mr. BENTLEY. I would think that that would be a consideration, absolutely.

Mr. PALLONE. But, you know, they're still competing with regard to price.

Mr. BENTLEY. That's right.

Mr. PALLONE. I just—you know, it's amazing to me when I see, you know, some of the things that the committee has uncovered. And, again, I want to thank you for all that you've done. I appreciate it. Thanks.

Mr. GREENWOOD. The gentleman yields back the balance of his time.

Does the gentleman from Texas seek recognition?

Mr. GREEN. Thank you, Mr. Chairman. I have just another series of questions for Mr. Bentley.

Mr. Bentley, you provided us with such an unprecedented view of the world of drug pricing, and it's not obviously a pretty one to those of us—who do you blame for this scheme, the drug companies or the providers or maybe those of us who passed the Balanced Budget Act in 1997 or 1996?

Mr. BENTLEY. I think there's enough blame that can go around for everyone. Certainly, you know, right now, as I've said, the manufacturers that are causing these inflated prices, they have it within their power to make the price changes immediately so that the programs can start achieving these savings that are very much needed. I don't know, other than their motives for profits, why they're not doing that.

Mr. GREEN. That's why people rob banks, too, their motive for profit. But later this morning we're going to hear from the American Association for Home Care, which is what your company did. You're a home health care company?

Mr. BENTLEY. Yes, sir.

Mr. GREEN. This witness will say that the infusion companies cannot make money if they don't get the inflated AWP. Is that true of your company?

Mr. BENTLEY. Well, I can't say that was absolutely true, because our company was merely a pharmacy. We worked in conjunction with home health and nursing agencies who actually went out and administered the drugs. And I will tell you this, that in Florida nursing agencies are paid separately for those services. So if there is an issue that a company is not able to hear, again like the oncologists get enough money on the professional side, I think that is a totally different issue than whether there are false prices being reported on pharmaceuticals.

Mr. GREEN. Did any of the groups, whether infusion companies or doctor/providers—did any of these groups go to the drug companies? Have you had any evidence that they asked for increases in the AWP so that they could survive or that—something that was already readily available?

Mr. BENTLEY. Absolutely. There's evidence in the committee's possession. There's a Baxter internal memorandum where they admit that raising their AWPs was a large part of their negotiations with two large national home health care companies. We're looking for it now.

Mr. GREEN. Okay. And that was already—that's in the documents?

Mr. BENTLEY. Yes, sir.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. BENTLEY. Here it is here. Increasing AWPs was a large part of our negotiation with the large home care companies. And, in fact, there's other documents in the committee's possession where there are providers and GPOs that actually go to the manufacturers and say, we're going to buy your drugs, our members will buy your drugs, and the basis is going to be on the greatest spread, and so we're telling you up front that is going to be the prerequisite as to whether we're going to buy your company's drugs or not. If you have the biggest spread, we'll buy yours over your competitor's.

Mr. GREEN. Mr. Chairman, do we have a copy of that memo that was just up? Is that available?

Mr. BENTLEY. Here it is here. H, low price and best spreads. Contract pricing will be evaluated on lowest price and/or best spread between AWP and the contract price for multisource products.

This was a GPO document. However, it was in the possession of a drug manufacturer who turned it over pursuant to the OIG subpoena.

Mr. GREEN. I'd like to see the whole document. I guess that is my concern, because I see quoted, and you said it was from Baxter?

Mr. BENTLEY. No, sir. This particular document was from Gerimed, which is a large group purchasing organization. But it was presented—or it was produced under an OIG subpoena, so I'm not sure which pharmaceutical company, one of the pharmaceutical companies.

Mr. GREEN. So your testimony is that——

Mr. GREENWOOD. Mr. Green, would you yield for a moment?

Mr. GREEN. Sure.

Mr. GREENWOOD. Would you identify the document in your hand?

Mr. GREEN. I was just looking for something that was reflective of this.

Mr. GREENWOOD. Did you give us the document number?

Mr. GREEN. Mr. Bentley must have that.

Mr. BENTLEY. It's probably in this book. I just don't have the tab.

Mr. LOCKWOOD. It's under O. Either 5 or 6.

Mr. BENTLEY. It's 05. It was produced by Dey Laboratories.

Mr. GREEN. So this information is that some of the providers obviously also worked with the manufacturers to game the system?

Mr. BENTLEY. I believe that Dey had this in their possession, because Gerimed had told Dey Laboratories that in order for Gerimed to consider whether their members would purchase Dey's products, they wanted Dey to know right up front that one of the requisites was going to be who was going to provide the biggest spread on their drugs.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. GREENWOOD. The time of the gentleman has expired.

Does the gentleman from Iowa, Mr. Ganske, seek recognition?

Mr. GANSKE. Thank you, Mr. Chairman.

Mr. GREENWOOD. The gentleman is recognized for 5 minutes.

Mr. GANSKE. Mr. Grob, I want to go over your recommendations in a little bit more detail. No. 1 says that we could look at authorizing a commission similar to MedPAC to set payment rates. Quote, it would then be granted authority to require manufacturers to provide them with drug wholesale prices.

Then on No. 2, you say we could calculate the national estimated acquisition costs based on average manufacturer prices, AMP, which you already testified some on, but you go on to say, we believe an initial intensive effort should be made to audit AMP data reported by manufacturers to validate its accuracy.

Mr. GROB. Yes.

Mr. GANSKE. No. 4 says, or we could increase discounting of the published AWP.

The point that I'm getting at is that—or even on No. 6, we could establish manufacturers' rebates similar to those used in the Medicaid. It would minimize manufacturers' incentives to inflate AWP.

But, anyway, the point I want to get at is we have to have accurate data.

Mr. GROB. Exactly.

Mr. GANSKE. Now, you mentioned a little while ago that CMS has data. How accurate do you think that is?

Mr. GROB. They don't have very much. They have some data that has resulted from some work with the Justice Department on a number of drugs that they were able to make available to the carriers earlier. That data is available—some efforts have been made, I think, as Mr. Bentley mentioned, to get some of the drug companies to produce more accurate prices in their public documents, but systematically the best source of data today is that average manufacturers' price, the actual manufacturers' price, which is submitted to CMS every year to be used in conjunction with the Medicaid program. That is the best data that is generally available and is updated, you know——

Mr. GANSKE. Well, how do you know that that's accurate?

Mr. GROB. We know that it's not completely accurate. That's why we said that would have to be audited. I don't know what data we could trust right now, except that with that data there already is a statutory requirement for it to be submitted to the Department. So there is an obligation for it to be done right.

If the manufacturers don't tell the truth there, then they have submitted false data. And the data then—it does come in regularly. So it is much more susceptible to definitions and audits than any other source, which comes from a variety of different sources and doesn't come so regularly. It's the best set that you could work with right now.

Mr. GANSKE. It seems to me that, you know—if you use that set or whatever, you're going to have to use actual—you're going to have to use actual invoices at some point to cross-check.

Mr. GROB. I think that that idea of the commission sort of encompasses that kind of thinking, that basically you would—I think you need a baseline of data, and then, if you want to, you can use sampling or other means in order to make sure it sounds realistic and that it really does reflect things.

What I was talking about earlier—and I wasn't meaning to respond specifically to another comment that you made—I don't think you'd want to do that for each and every payment that each and every physician makes each and every time. I think that would be overwhelming. But I do think that your point is a good one that trying to get some real live market data, at least on a sampling basis, in order to see if what you have is real I think is a good idea.

Mr. GANSKE. I'm very interested in this. Because as Congress looks at providing increased prescription drug coverage for Medicare, one of my ideas has been that we utilize the State Medicaid drug programs and extend that benefit to the qualified low-income Medicare beneficiaries, CLMBs, SLMBs and others. It's clear we need to make sure that, you know, that program is utilizing accurate data as well.

Mr. GROB. That, by the way, is an excellent point I think, for efficiency. Because again—laying aside the other part of the Medicaid, their use of AWP and this kind of thing, which has the same problems if not worse than Medicare in some cases—going back to the single data source, I think the point is excellent, because then you would have one set of data, which the manufacturers are saying is correct, submitting it to the government under a statutory require-

ment, subject to audit and review. It forms a good base case for anything else you want to do.

Now, you could then take that base case, you could, say, make our percentage higher than that, or something lower. You could then test it with some samples. But it gives you a nice centralized piece. When we tried to come up with these ideas, we know that none of them will work perfectly, but we were looking for some practical ideas, something that is within the means to actually do it. That one kept emerging as one of the good starting points, if you will, for data.

Mr. GANSKE. I thank you. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman.

The Chair thanks the witnesses for their 3½ hours of endurance. Your testimony has been extremely valuable to us, and the interest has been high. We appreciate your contributions. Thank you, and you are excused.

Mr. GREENWOOD. Now we call forth Mr. Thomas Scully, the Administrator for the Centers for Medicare and Medicaid Services; and we thank you in advance for your forbearance. As has been your habit, you have been here for the entire hearing, and probably only adding to the agony of waiting is watching the membership dwindle from 25 to three. But we look forward to your testimony.

Mr. SCULLY. Thank you, Mr. Chairman, Chairman Tauzin, Mr. Brown——

Mr. GREENWOOD. Before you begin your testimony, you're aware, Mr. Scully, that this is a joint hearing between the Oversight and Investigations Subcommittee and the Health Subcommittee, and it is our practice—the practice of the Oversight and Investigations Subcommittee to take our testimony under oath. Do you have any objections to testifying under oath?

Also consistent with the rules of the House and the committee, you have the right to be represented by an attorney. Do you wish to be represented by an attorney?

Mr. SCULLY. I used to be a bad attorney.

Mr. GREENWOOD. So saying, I'll administer the oath.

[Witness sworn.]

Mr. GREENWOOD. You're now under oath, and you're recognized for your testimony.

TESTIMONY OF THOMAS A. SCULLY, ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES

Mr. SCULLY. Thank you, Mr. Chairman, for having me.

I will quickly get to AWP. I'm not sure how much I have left to add after that, but a few ideas I hope.

If I could, just quickly, before I get to that, I just wanted to thank a lot of the—you talked about New York earlier, and I'd just like to thank the New York hospitals who we spent a lot of time working with the last few weeks. I wish we had more people in the hospitals. But a lot of you also don't realize that outside the hospitals in the bottom part of Manhattan there are also a lot of disabled people that weren't getting home health. And since I have a chance to publicly, I'd like to thank the home health agencies. The Visiting Nurse Association of New York was particularly terrific in the last 2 weeks. But I think a lot of the health care problems that

weren't directly related to the World Trade Centers in the southern Manhattan have been dealt with incredibly well by the City, the State and hopefully with a little bit of help from CMS but with a lot of help from some incredibly selfless providers in lower New York.

Second, if I could just before I get into the AWP issue, one issue that I've become extremely focused on the last 2 weeks since I've now been at the CMS about 3½ months has been a problem you're probably going to get to, if not this year certainly next year, which is HIPAA compliance. And I've recently been extremely focused in the last week on the fact that, like it or not, in a year we have to have a completely new coding system put in place for all providers—Medicare, Medicaid, everyone else.

I don't think I've talked about it enough since I've been on the job. I've only recently begun to understand what a gigantic mission that is, and I think it's obviously like Nancy-Ann's mission to focus the industry on Y2K; and my predecessor, I think it's our mission in the next year to focus people on HIPAA. And whether Congress changes or delays the law or not, we could have a debate about that, I'm sure, at a future time. We have a big, big mission in front of us with HIPAA in the next year, and I intend to—in every speech I give and every time I testify or talk about it, if nothing else, raise the awareness of providers that we have a major, major change in the health financing system that we have to deal with outside this.

Anyway, switching back to HIPAA, the one thing I can say to start with—and I'll try not to go through every issue again—is we agree. And my frustration with the hearing, if anything, is that I hope most of the members that were here didn't leave with the idea that CMS all the way back to Bruce Lanakin before has not been focused on this. And the press also may have already left.

I was involved in this in 1991 in the first Bush administration. We tried to fix it, and there's a long track record from 1991 to 1992.

I was very involved, by the way, in Andrews Air Force Base in creating Medicaid drug rebates with Chris Jennings who was on the Hill, President Clinton's most recent—so I have a long history in Medicaid drug rebates.

This whole issue, people have been trying to fix this for years. And back to Secretary Shalala and Nancy-Ann DeParle last year, they tried to fix it. Got an outpouring of screaming from every affected party, appropriate or inappropriate, and then were hit with a Congressional prohibition for a year not to look at it.

So where we are currently at CMS is we're prohibited, until the GAO report that came out today and until the Secretary reads it, is what the law says, we cannot respond to it. Certainly it will take us a while to put out a rule. But also we're required by law to pay 95 percent of AWP.

Now, could I creatively go back and change it? I'm sure we probably could, and we'd be willing to look at that, but I also have no doubt we'd be sued and it's not the easiest way to fix it.

So I'm here to talk about a number of issues today, but one thing I would ask for is I think this cries out for a legislative solution. We're very anxious to work with you on a legislative solution. I

hope we can do it this year before you leave, and we'll give all our staff resources and everything we can to help you fix it. It's an issue that's been around for a long time, and I'm excited that Chairman Tauzin, you, Mr. Brown, Mr. Deutsch and everyone else seem to be in agreement that we need to fix it; and whatever help you need from CMS on a technical basis to fix it, we are very, very anxious to do so.

We have been paying more than any other purchaser for Medicare drugs on an outpatient basis for a long time, and we're determined to get the price down to a reasonable level. What that is, I'll try to give you a few ideas.

In the meantime, I do think, however, the concern—it is a legitimate concern for the providers—is that if you're going to lower—do we always fix the right price in Medicare, which is what we do for providers? Probably not. Do we have the right price for oncologists and their practice expenses? Probably not.

I think at the same time we reduce the prices for the drugs we need to go back and look at oncologists. I think we probably need to look at the ESRD clinics, dialysis centers that also use these drugs quite a bit. Hemophiliac agencies also rely on this to a large degree. DME providers probably have some argument.

I'm not saying they should all have their rates increased, but there is a substantial amount of money to be saved here. And I think at the same time we do that I think we should also go back and look at the base payment rates and make sure there's a balance. I have very little doubt it's not dollar for dollar, as you're aware and we've talked about, but I do think it's appropriate to make sure that, to the extent we can set prices right for drugs, then for practice expenses, then for practice patterns, we should set them right. And I think there's very little doubt they're not right right now.

But in fairness to Nancy-Ann DeParle, my predecessor in the agency, I think this is something the agency has been trying to do for years, and every time it's put its head up, it's got creamed. So we're anxious and excited that many Members of Congress are now aware of it and are interested in fixing it as well.

Let me just talk quickly and give you a couple of suggestions. One is, Mr. Deutsch and Chairman Tauzin both mentioned that this is not just a problem with the Medicare program, it's a huge problem for beneficiaries. And I totally agree. The fact that the beneficiaries pay the 20 percent copayments is a gigantic problem. There are a lot of things wrong with the Medicare problem. There are very few places where beneficiaries feel the inequities of the program as much as they do here. So I think it's important that the chairman focused on that, and I think that we need to focus on that in the fix. Seniors are paying a big chunk of the inequities in the drug payments that we have here.

Second point, 20 drugs account for 75 percent of the spending in this area. So do we have the tools to look at it? We do, and we can talk a little bit about Medicaid and what we have available in Medicaid. The numbers are big, but the number of drugs you're dealing with are relatively small. Single source drugs account for 60 percent of all the Medicare drug spending. So it's relatively narrow. The numbers are big, but the numbers of drugs we're talking about

are relatively narrow. So I think if we focus on this problem, hopefully legislatively, it is very fixable.

A fourth point I'd make is that I think we need to be sensitive. Physicians do in fact—back as far as I believe it was 1997—actually it was 1991 was the first time I believe that then HCFA proposed to have 85 percent of AWP. Then physicians came back and said we can't get it for 85 percent of AWP. And that may be the case. I think it's important when we look at new reimbursement systems that we understand it's not like the Federal supply schedule where the VA sets prices. Doctors actually have to go out and buy this on the market. And while the prices may be outrageous, they actually have to go get it.

So our real issue is to focus on the manufacturers and how we get the money back at the end of the game from the—to the manufacturers—hopefully no game at the end of the day from manufacturers. And it is a legitimate problem that physicians out there around the country can't always get it for less than a certain amount of AWP.

So I think we need to look at the bottom line of what the program is paying without squeezing providers to the point where physicians out there in the real world can't get ahold of it. And I think in our legislative—hopefully legislative fix, we need to look at that.

There are a number of different approaches that you have talked about, and I'll just try to run through a couple of them that I think are possible.

The Federal supply schedule has been mentioned. I think that when you look at the VA and when you look at the agencies, Coast Guard and others in the Federal supply schedule, it's really not an apples to apples comparison. I think that probably wouldn't work. Those are really Federal agencies buying the drugs for direct use in Federal agencies.

Average manufacturers' price, which is the bottom line number that was used in the Medicaid program, and we do in fact have those numbers and they are audited and I think they're pretty solid, but again, by statute they're confidential and we're not allowed to use them. In fact, our Medicare staff doesn't have access to them. Only the Medicaid staff does. So is that a more legitimate number? Absolutely.

I think there may be some problems there, but average manufacturers' price, which GAO seemed to suggest is a very auditable and very reasonable number, I think if you went to average manufacturers' price, you might run the risk of squeezing access to physicians out there in the market trying to buy them. So I think there's a possibility.

I think the Medicaid program has some flaws, but there's a model there, and I'll suggest that in a second.

You've talked about wholesale acquisition costs which I think is a better price than AWP. But, again, AWP is largely air, and I think wholesale acquisition costs may be a little better, but it's still potentially air, and you can raise it and lower it as you like, and I think it's a very—the potential for manipulation of that is relatively high as well. As a short-term fix it might work, but I think there are probably better ones.

People have proposed that we do a survey of market prices, which also might work. I talked to my staff about trying to do a survey of what nursing homes pay, for instance, because nursing home chains usually have—they're not as big as the Federal supply schedule, but large nursing homes, Manor Care, somebody like that frequently buys—you know, has a similar group of patients buying in large bulk volume.

The problem in doing that—and I think that's a possibility—is that you're looking back a year. And obviously, as you can see from the earlier testimony, the prices change by the day, and looking back and doing a snapshot looking back a year at anybody, for us to do a survey of 2000 prices to set 2001 prices is never going to be quite right. So I think that has its flaws as well.

There is a concept similar to average manufacturers' price called average sales price that you could possibly use, but I think a combination of these we certainly could work on legislatively, and I think the bottom line is that the manufacturers know at the end of the day how many units they're selling to Medicare. They know how many we're paying for.

If we can, in fact, require them, as we do in Medicaid, to tell us what the price is and calculate at the end of the year how many they sold to Medicare and what the price is and recover that price and there is a mechanism to do that, I think to find that balance that we end up getting the right price charged us by the manufacturer, while not limiting and denying access to the physicians that are actually out there in the market, potentially in a small town trying to get it, is the mix that we need to find, and I think it's very doable.

Can we do this administratively? I think we probably won't in the near term, because we probably would get sued. We'd certainly prefer to do it legislatively. I think we could. And if Congress doesn't act, it would probably take us a year to a year and a half to do it. It would take a long rulemaking process. I have zero doubt that we'd be sued, because of what the law says on 95 percent of AWP.

So I would strongly, strongly, strongly prefer to work with Congress hopefully in the next month to find a legislative solution that works, that is fair to the oncologists, that is fair to the dialysis clinics, that is fair to the other patient groups involved and that gets our payment back on the right track. Because it's clearly a very messy system we're in right now.

So I know you've had a long hearing already. That's about as fast as I can talk, and I skipped over a whole bunch of other things I was going to say, but I hope—it may be more valuable just to answer questions. But there is zero doubt that the administration, while we don't have the set solution, is extremely interested in working to fix this problem.

[The prepared statement of Thomas A. Scully follows:]

PREPARED STATEMENT OF THOMAS A. SCULLY, ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

Chairman Greenwood, Chairman Bilirakis, Congressman Deutsch, Congressman Brown, distinguished Subcommittee members, thank you for inviting me to discuss Medicare payment for outpatient prescription drugs. As you know, prescription drugs are becoming an increasingly important component of modern health care,

particularly for Medicare beneficiaries. We are working with Congress to modernize Medicare to cover prescription drugs and provide relief to seniors from high drug costs. In addition, it is clear that the payment system for selected outpatient drugs that are now covered by Medicare is a mess. Medicare now pays more than many other purchasers for the drugs we cover due to the way that drug manufacturers report their prices and Medicare's payment policies. Medicare should pay appropriately for all Medicare benefits, including the drugs we currently cover, and it is unacceptable that the current system results in Medicare paying excessive prices. We also need to pay appropriately for the services required to furnish these drugs. I appreciate your dedication and leadership on this issue, and I look forward to working with you and your colleagues to ensure that Medicare beneficiaries have access to the drugs they need and that Medicare pays competitive prices for these prescription drugs.

By law, Medicare does not pay for most outpatient prescription drugs. However, there are some specific exceptions where Medicare covers pharmaceuticals, such as drugs furnished incident to a physician's covered services, and in these cases, the law mandates that we pay physicians and other providers based on the lower of the billed charge or 95 percent of the drugs' average wholesale price (AWP). Numerous studies have indicated that the industry's reported wholesale prices, the data on which Medicare payments are based, are vastly higher than the amounts that drug manufacturers and wholesalers actually charge providers. That means Medicare beneficiaries, through their premiums and cost sharing, and U.S. taxpayers are spending far more than the "average" price that we believe the law intended them to pay. Some affected physicians and providers have suggested that they need these Medicare "drug profits" to cross subsidize what they believe are inadequate Medicare payments for services related to furnishing the drugs, such as the administration of chemotherapy for cancer. I believe we need to pay appropriately for both the drugs and the services related to furnishing the drugs.

Clearly, Medicare drug pricing is a complex issue. Over the years, numerous legislative efforts have failed to develop an effective alternative to AWP and ensure that Medicare and its beneficiaries do not pay more than they should for the limited number of prescription drugs that Medicare covers. We are committed to working with Congress on a bipartisan basis to ensure that Medicare pays accurately for all of its benefits. As we look to the future, particularly in the context of developing a Medicare drug benefit that does not make the same mistakes, I think it might be important to review previous efforts to reform the AWP payments so that together we can develop a workable solution.

MEDICARE'S LIMITED DRUG BENEFIT

The Centers for Medicare & Medicaid Services (CMS) pays most of the health care expenses of almost 40 million Medicare beneficiaries. If we were creating the Medicare program today, a prescription drug benefit certainly would be included. However, in 1965, prescription drugs played a less prominent role in health care, and the emphasis then was on ensuring access to inpatient hospital care in Medicare Part A and providing access to physicians in Medicare Part B. Today, Medicare beneficiaries rely on prescription drugs as an integral part of their health care. Although by law, Medicare does not generally cover over-the-counter or outpatient prescription drugs, currently Medicare does cover some drugs, including:

- Drugs that are not self-administered and furnished "incident to" a physician's service, such as prostate cancer drugs;
- Certain self-administered oral cancer and anti-nausea drugs;
- Certain drugs used as part of durable medical equipment or infusion devices, (e.g., the albuterol that is put into nebulizers, which are devices used by asthma patients);
- Immunosuppressive drugs, which are used following organ transplants;
- Erythropoietin (EPO), far and away the drug Medicare spends the most money on, is used primarily to treat anemia in end stage renal disease patients and in cancer patients; and
- Osteoporosis drugs furnished to certain beneficiaries by home health agencies.

These drugs are typically provided in the hospital outpatient setting, dialysis centers, or in the doctor's office, and are purchased directly by the physician or provider. Additionally, vaccines for diseases like influenza, pneumonia, and hepatitis are considered drugs, and are covered by Medicare.

By law, we generally pay for these drugs based on the actual charge or 95 percent of the AWP, whichever is lower. This adds up to more than $5 billion a year for currently covered drugs, approximately 80 percent of which is paid for by the Medicare program. In general, Medicare beneficiaries must also share in the cost of pur-

chasing these drugs through their Part B premiums, and except for the flu and pneumonia vaccines, the $100 Part B annual deductible, and a 20 percent coinsurance.

MEDICARE PAYMENT FOR CURRENTLY COVERED DRUGS

The AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies. Traditionally, AWP has been based on prices reported by drug manufacturers and published in compendia such as the Red Book, which is published by Medical Economics Company, Inc. However, manufacturers and wholesalers increasingly give physicians and providers discounts that reduce the actual amount that the physician or provider actually pays for the drugs. These discounts are not reflected in the published price and reduce the amount providers actually pay to levels far below those prices published in the Red Book. Furthermore, use of the AWP, as reported by manufacturers to companies which compile such prices creates a situation where a manufacturer can, for certain drugs, increase the reported AWP and, in turn, offer physicians a deeper discount.

This Committee, CMS, the Department's Office of the Inspector General (IG), and others have long recognized the shortcomings of AWP as a way for Medicare to reimburse for drugs. The IG has published numerous reports showing that true market prices for the top drugs billed to the Medicare program by physicians, independent dialysis facilities, and durable medical equipment suppliers were actually significantly less than the AWP reported in the *Red Book* and like publications. As competitive discounts have become widespread, the AWP mechanism has resulted in increasing payment distortions. However, Medicare has continued to pay for these drugs based on the reported AWP amount. By offering physicians and providers deep discounts compared to the price they could bill Medicare, the drug manufacturers are able to use profit margins to manipulate physicians and providers to use their products for Medicare beneficiaries. It is simply unacceptable for Medicare to continue paying for drugs in a way that costs beneficiaries and the program far more than it should.

In the past, the Agency has attempted to remedy disparities between Medicare payments based on AWP and the amount actually paid competitively by physicians and providers. However, these efforts have not been successful. For example, in CMS/HCFA's June 1991 proposed physician fee schedule, the Agency proposed that payment be based on 85 percent of AWP. We also proposed that certain very high volume drugs be reimbursed at levels equal to the lesser of 85 percent of AWP or the physician's or provider's estimated acquisition cost. We received many comments, primarily from oncologists, indicating that this 85 percent standard was inappropriate. Most comments indicated that while many drugs could be purchased for less than 85 percent of AWP, other drugs were not discounted. Others suggested that while pharmacies and perhaps large practices could receive substantial discounts on their drug prices, individual physicians could not. As an alternative, beginning with 1992, a policy was established for Medicare to pay the AWP or the estimated acquisition cost, whichever was less.

Since the Estimated Acquisition Cost approach proved to be unworkable, subsequent legislation was proposed that would have required Medicare to pay physicians their actual acquisition cost for drugs. Under this proposal, physicians would tell Medicare what they paid for the drugs and be reimbursed that amount, rather than the Agency developing an estimate of acquisition costs and paying physicians based on that estimate. After considering this proposal, Congress adopted an alternative approach in the Balanced Budget Act of 1997 (BBA), setting Medicare's payment for drugs at the lesser of the billed charge or 95 percent of AWP. While this brought Medicare payments closer to the prices that physicians and providers pay for drugs, Medicare payments were still significantly greater than the competitive discounts obtained by physicians and the system still tied Medicare payments to the artificially inflated industry-reported list prices. In fact, in a December 1997 report, the IG found payments based on AWP to be substantially greater than the prices available to the physician community. As an alternative to actual acquisition costs, Congress considered proposals to pay all Medicare drugs at 83 percent of AWP, a compromise between 95 percent of the AWP and the average discount found by the IG.

In May 2000, the DOJ and the National Association of Medicaid Fraud Control Units made accurate market wholesale prices for 49 drugs covered by Medicaid available to State Medicaid programs and to First Data Bank, a drug price compendia owned by the Hearst Corporation. These wholesale prices, culled from wholesale catalogs circulated among the provider community, reflected the actual Average Wholesale Prices for these drugs far more accurately than the drug manufacturers'

AWP. Last year, HCFA sent this new information to Medicare carriers and instructed them to consider these alternative wholesale prices as another source of AWP data in determining their January 1, 2001 quarterly update for many of these drugs. However, due to concerns about Medicare payments related to the administration of the chemotherapy and clotting factor drugs, the Administration instructed our carriers not to use the data for those drugs at that time.

In December 2000, Congress enacted the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA), which established a moratorium on decreases in Medicare drug payments while the General Accounting Office (GAO) conducted a study of Medicare drug pricing and related payment issues. HCFA postponed Medicare carriers' use of the DOJ data until we could review the GAO report. We look forward to reviewing the GAO's findings and working with you to revise Medicare's drug payment policy. We must ensure that beneficiaries and Medicare pay appropriately for both the drugs that we cover and the services related to furnishing the drugs.

CONCLUSION

Medicare beneficiaries rely on prescription drugs, and the coinsurance they pay for covered drugs is tied directly to the prices that Medicare pays. We must find a competitive way to ensure that Medicare beneficiaries and taxpayers are no longer paying excessive prices for drugs that are far above the competitive discounts that are widely available today. We need to pay appropriately for all Medicare benefits, including the prescription drugs we cover and the services required to furnish those drugs. We look forward to reviewing the GAO report, and working with you Mr. Chairman, this Subcommittee, and the Congress to revise Medicare's payment policy for currently covered drugs. Thank you for the opportunity to discuss this important issue with you today, and I am happy to answer your questions.

Mr. GREENWOOD. Thank you, Mr. Scully. We appreciate your testimony and your presence and again your endurance in staying with us all this time.

Let me, first of all, comment on why the 85 percent of AWP obviously won't work. Because, as we've seen, some AWPs are actually straight; and particularly when there's no competition there's no incentive for the drug companies to falsify the AWP. So to reimburse 85 percent wouldn't be fair for those who are paying a hundred percent of the AWP, because the physicians would lose money every time. So clearly that won't work.

We do have five principles that my staff and I have worked out in terms of what we think the direction of the legislation that we hope to enact into law in the next month is, and I'd just like to tick these off for you and see if we have general conceptual agreement on how to proceed.

No. 1 is that any new drug reimbursement should not adversely impact Medicare patient access to quality health care. Would you like me to repeat that?

Mr. SCULLY. I'm sorry. I was trying to find your——

Mr. GREENWOOD. The question is, would you agree in concept with these five principles for legislation: Any new drug reimbursement should not adversely impact Medicare patient access to quality health care?

Mr. SCULLY. Sure. Absolutely.

Mr. GREENWOOD. That is a no-brainer.

Mr. SCULLY. That was an easy one. Thank you.

Mr. GREENWOOD. Medicare's reimbursement for coverage drugs should be closely linked to the prices that providers actually pay for the drugs.

Mr. SCULLY. I think that is the bottom line goal, yes.

Mr. GREENWOOD. Three, Medicare services and administration should be reimbursed according to their costs, exclusive of any reference to drug reimbursements?

Mr. SCULLY. The only caveat I'll put into that is, having been in the hospital business for years, costs—but, yeah, actual, real expenses, yes, because cost is what we paid for for years, and that is real life.

Mr. GREENWOOD. Understood.

Fourth, the impact of Medicare's drug reimbursement policies have—upon the making of clinical decisions should be eliminated or reduced to the greatest extent possible.

Mr. SCULLY. Yes. I think absolutely.

Mr. GREENWOOD. Okay. And, fifth, Medicare's reimbursement for treatments in related settings should be equalized to discourage migration between settings based upon relative levels of profit available to providers.

Mr. SCULLY. Yes.

Mr. GREENWOOD. Bottom line there is we don't want to drive these patients certainly back to a hospital setting which costs Medicare more and is sometimes a less pleasant experience for the patient.

Let me ask you this. These principles are not rocket science. This is a very manageable issue, as far as I'm concerned, based on my research here. The GAO report today gives us the foundation in terms of the expenses or costs for the oncologists. I hope we'll erase what has been an obstacle before, which is the legitimate concern raised by Members of Congress, frankly, because we do not have the data to forestall anything that might have some of these adverse effects on patients or providers.

If in fact we can put a legislative solution into some kind of an omnibus package that we sign into law—have signed into law, let us say sometime in October, do you have a sense from talking with your staff yet how long it might take CMS? How much time do you need to enact this so that we get a good system that works well, meets all of these objectives and begins to save the beneficiaries and Medicare the billions of dollars that we've talked about?

Mr. SCULLY. Well, clearly you can start paying different drug prices in AWP pretty quickly. The real issue is making—I think there is some legitimate argument that oncologists, as I mentioned, dialysis clinics—there are a variety of practice groups, at least an argument I've heard, on DME providers. The issue is that we put out our rates on January 1. Most of those rates are already in place. The systems are hard to change. The issue is from an equity point of view, and if there are providers that rely on inappropriately high AWP payments——

Mr. GREENWOOD. If I may, I should have included—incorporated that in my question. But if we give you the objective of coordinating in time this two-step process, move from AWP to a more cost-related—price-related reimbursement rate and reset the practice expense and the reimbursements for these specialties who are—specialists who will in fact lose revenue as a result of this change, how long would that take?

Mr. SCULLY. The quickest way we could rationally do it—again, I can tell you what my—all the people that have to do the actual

work, which a lot of people forget. There's actually lots of people in Baltimore here that have to actually do this. The quickest way you really do it is fiscal year 2003, for the fee schedules that come out in January of 2003, because that is really only the time you go back and recalibrate up the practice expenses and everything else.

It's possible—nobody is happy with this answer in CMS, I can tell you, but it's possible that if you directed us and you put money into the second half of 2002, that for the last two quarters of 2002, we could possibly—and I'm not even certain of this now—recalibrate some of the payments up.

We certainly can pay less on AWP, but if you're trying to find the balance, what I've heard from oncologists and others is, if you're going to cut the AWP, which we rely on, you need to fix the practice expense at the same time and in the same bill. I imagine they wouldn't be very happy to have the drug reimbursement cut at the same time the practice expenses don't go up. So pushing the envelope as much as it possibly can be—and I can tell you this is an extremely unpopular opinion with the staff at CMS—the fastest we could possibly do it is probably next July, and under normal circumstances, the fastest we could do it is January of 2003.

Mr. GREENWOOD. That is very helpful. I appreciate that.

My time has expired. The Chair recognizes the gentleman from Ohio, Mr. Brown, for 5 minutes.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. Scully, nice to have you in front of the subcommittee.

You have the authority now to use an inherent reasonableness standard to reduce reimbursements for Medicare drugs which basically bear no resemblance to actual costs or actual cost plus. Do you have that story?

Mr. SCULLY. I think we do. I think the issue here is, as I mentioned, the agencies have a hard time getting around that. We actually sent out guidance of what we thought was an AWP—not me, but, as you know, Nancy-Ann DeParle and Secretary Shalala—about a year and a half ago to have our carriers interpret what was a low AWP, and there was quite an uproar about that, and the result of it was a legislative prohibition about changing it. So it's very debatable from a legal point of view as to whether we do have the authority. So if Congress doesn't act, we'll certainly look into it, but it would be far preferable to have legislative guidance.

Mr. BROWN. Wasn't there a GAO review and they said it was adequate? GAO did a review and said it was adequate?

Mr. SCULLY. A review of the practice expenses or the——

Mr. BROWN. Of the inherit reasonableness.

Mr. SCULLY. I think I read the report last night, and I think that—their view was we have an inherent reasonableness authority to interpret what the AWP is, and I believe he said in his testimony that it says average wholesale price in the statute. But as a former pretty bad lawyer, somebody who has had—been sued numerous times this fall, I would say that with the track record of having the government use the AWP for 30 years, I would have very little doubt that our authority to do that would be challenged. We certainly are willing to do it if it comes to that, but it would be much sounder I think if we get legislative guidance.

Mr. BROWN. Would it be appropriate first, Mr. Chairman, or Mr. Scanlon to address that, that the GAO did in fact find that. Correct?

Mr. SCANLON. We reported on the expedited inherent reasonableness authority that you gave to the agency in the Balanced Budget Act which allows for up to a 15 percent reduction, again, in an expedited fashion. Whether we have the ability to redefine AWP and define it any way we'd like is a somewhat dicey legal issue. We're happy to—believe me, we're very anxious as you are to fix this. I would say it would be certainly much more likely to succeed if we had additional legislative guidance.

Mr. BROWN. Could you submit a legal opinion for the record on that?

Mr. SCANLON. Sure.

Mr. BROWN. Let me shift gears for a second. Before that, I just—if in fact you can do that, using an inherent reasonableness standard to reduce reimbursements, I would hope that CMS could be more aggressive. I guess you have a pilot project in Texas and look to do more of that for competitive pricing in the months ahead.

All the talk about the solutions that have been bandied about in the prior panel and from opening statements and others, if Medicare changes the way that Congress pays for prescription drugs, obviously then changing the reimbursement rate for oncologists and saying that the practice expense payment system needs to be adjusted, what does that do—my understanding is the entire pool of practice expense payment needs to be budget neutral. Does that mean any increase in practice expenses for oncologists would then cause a reduction in practice expenses for other specialties?

Mr. SCULLY. Well, under current law it would or wouldn't change, and I personally would not recommend us doing that, because I don't think we should be taking funds from other practice expenses to fund oncology. I think the discussion that's been had in some quarters about legislation is that if you're going to change the AWP legislatively you will get significant baseline savings, and some of that could go back into just adding in a nonbudget neutral fashion back into the practice expense pot, which you can do legislatively to increase, where appropriate, some practice expenses in some areas without taking it from others.

But, clearly, without legislation, any practice expense change has to be budget neutral.

Mr. BROWN. So if we were to do that, do you have any suggestions on the amounts of—you, first of all, say we in a sense legislatively break the budget neutral concept of practice expense, at least for this particular case. What kind of money do you talk about in terms of the oncologists then versus what we've done?

Mr. SCULLY. Chairman Greenwood and I talked about this a little bit, and he—apparently in the GAO reports read last night, they suggested $51 million. It's not always easy to get a quick back-of-the-envelope read from my staff, but I think that number is in the ballpark. It's close, somewhere in the 40—I mentioned to him that our back-of-the-envelope number was pretty close to that, in the $45 to $55 million range.

Mr. BROWN. What are you hearing from other physicians, other specialties about the practice expense issue?

Mr. SCULLY. You know, in fairness, I was one of the drafters of my first job and the first—one of my first jobs in the first Bush administration was passing RVRS in 1989, since I was primarily responsible for the administration's position back then.

One of the reasons I like it——

Mr. BROWN. A lot of complaints should be directed to you then.

Mr. SCULLY. Yeah. It's all my fault. They didn't like it much back then, but, in fairness, I think the system has worked reasonably well. If you look at all the other reimbursements over the last 15 years, nursing homes, hospitals, everything else has been an up-and-down roller coaster. Physician reimbursement has been relatively—as I'm sure the physicians on the committee might not agree, but I think generally even the AMA would tell you that, relative to other reimbursements in Medicare, it's been more predictable and more stable and the system has worked reasonably well.

The thing about practice expense is that basically we rely 98 percent of the time on the—what's called the RUC, which is essentially the committee through the physician groups to recommend what the practice expenses should be. So if the oncologists think they're underpaid, they have to come argue why it should come out of the oncologists versus the surgeons, versus the gastroenterologists, and they sit around a table every year and make recommendations, the vast majority of which we take. But it's a finite pot, and I think it works reasonably well.

So the issue here is—it's the physicians all sitting around the table with CMS saying who is underpaid and who is overpaid, and they're all arguing over a finite pot that you've authorized. And I think it works actually reasonably well. I mean, everybody is unhappy, but once everybody is unhappy that usually means it's working right.

Mr. BROWN. Thank you, Mr. Chairman.

Chairman TAUZIN. I thank my friend. The Chair recognized him so briefly for a round of questions.

Thanks for coming, Mr. Scully. Of course we appreciate you being here.

Let me ask you in regard to that finite pot. If we are going to work out a solution that establishes a responsible AWP, something more akin to the real cost of the drug, and it reduces the income to the oncologists significantly and the oncologist does have a claim that he is under-reimbursed for practice expenses, which you and I think GAO both have conceded is true, at least to some extent—you've identified it around $50 million. If we simply say that we're going to permit the oncologist to have a larger share of that finite pool, does that ipso facto mean that other physicians, other service providers will lose reimbursement as a result?

Mr. SCULLY. If we were directed to do that administratively without new money in the pot, it would, but my hope would be that in the same—what I've heard from responsible oncologists, of which there are many, is that they agree that many of the things in the system are broken and in fact if we fixed in the same bill simultaneously AWP and adjusted their practice expenses, they don't think that is necessarily unfair. Now some may disagree with that.

Chairman TAUZIN. Provided we increased the pool to accommodate to whatever few reimbursements we ought to provide for those physicians. Is that correct?

Mr. SCULLY. Once again, in fairness, Mr. Chairman, I think—and I'd like to work with your staff on—I do think it's not oncologists who've made the most noise on this. I do think dialysis providers of a number of drugs and I think hemophilia agencies do. And, to a lesser degree, we ought to look at other providers and make sure they also are made whole.

Chairman TAUZIN. We've got to look at every single provider that may be losing income as a result of a change in AWP and examine whether or not in fact their practice is being properly reimbursed under the current system. Is that correct?

Mr. SCULLY. Yes.

Chairman TAUZIN. And we need to come up with a number that we need to add to the pool to make it fair, and there is a disagreement on that number, right? I mean, you and GAO have a number around 50——

Mr. SCULLY. Pretty close. I think we're pretty close.

Chairman TAUZIN. I've heard some extraordinary numbers coming from some of the care providers. So we're going to have to somehow provide some rationale for a proper number. Is that correct?

Mr. SCULLY. Yes, sir.

Chairman TAUZIN. Second, why don't you now use the average manufacturers' price and best price under the Medicaid rebate program in establishing an average wholesale—or average wholesale price? I think I know the answer why you don't, but tell me.

Mr. SCULLY. I believe it's statutory. That's another thing that I hate to say that I helped create at Andrews Air Force Base in——

Chairman TAUZIN. So if you're going to use it, we have to change the law?

Mr. SCULLY. If you wanted—the way it works is we do use average manufacturers' price, I believe, and my staff might correct me if I'm wrong, but the rebate—it comes up that the difference between the AWP that's charged and the average manufacturers' price is just a small piece of it. So you could, in fact, correct Medicaid law as well and arguably make it more appropriate.

Now, the two sides—just to give the other side, you probably hear from private insurance companies is there's no doubt what we're paying in Medicare in a big way and arguably in Medicaid in a smaller way, but when you put those two programs together and you squeeze the pot that's going to bounce back on the private insurers. So—to some degree.

Now, there's no question to some it's excessive margin. But if you take Medicare and Medicaid which are—at least in the hospital outpatient setting, 40 percent of that is usually Medicare. Maybe 12, 14 percent is Medicaid. Then you squeeze down on their reimbursement there, which we certainly need to do, you're going to have the insurers and others on the private payer side come back and say our drug prices just went up.

Now, again, I would very much doubt that is a wash. I think the margins on the Medicare side are extreme, to say the least.

Chairman TAUZIN. And you both tend to say that. We have at least some evidence coming in from the other side claiming that it's a wash. We're going to have to again get some sort of arbitration on that number to find out what it is.

Mr. SCULLY. I think generally the insurance plans are—you know, they have the flexibility to negotiate prices, and they generally can fend for themselves pretty well, but you will hear a push back from the other side.

Chairman TAUZIN. Let me ask you a very simple question that I think I know the answer to, but you might give us some insight on it. Why on earth do we have a system that requires a Medicare beneficiary to pay 20 percent as a copay of an artificial price? It can exceed the real cost of the drug to the physician. What would happen if the law would change or some provision were made, either administratively or by change of law, to require that the 20 percent copay would be 20 percent of the real price paid by the care provider for the drug? What is wrong with that?

Mr. SCULLY. Other than the budget spending, it sounds like a great idea, and I think——

Chairman TAUZIN. It would save American patients $177 million that they're spending on excessive copays, because copays are based on fictitious numbers. I mean, when a patient has to pay 500 percent for this one drug I cited of the amount the doctor is having to pay for that drug as a copay, I mean, citizens look at that and say, you know, that's Alice in Wonderland. It's just crazy. Shouldn't the copay be based upon the real cost of the drug to the doctor, and what would it take to do that?

Mr. SCULLY. Well, that may be—that gets into the delicate difference, as I said. But we can probably figure out exactly what we should be paying the manufacturers and recoup it, much the way Medicaid does through a reconciliation.

The issue is, if you're trying not to squeeze, the physician is trying to buy it out in the market at the beginning of the year. Finding out what—the right number to charge the 20 percent copay against is one the tougher things to figure out.

Chairman TAUZIN. It is not hard to figure out. You simply have a provision that says you can't charge the doctor or physician as a co-pay more than 20 percent of the drug——

Mr. BROWN. Will you be able to do that administratively, the chairman's suggestion, simply so that the patient would pay the 20 percent of what the actual charge, what the doctor's actually charging for the drug? Could you do that?

Mr. SCULLY. Well, the closest thing we have right now, the ability to actually determine what the actual price paid is, is the average manufacturer's price which we have for the purposes of Medicaid the worst——

Chairman TAUZIN. Let me say it again. If the law said that the doctor can't charge the patient more than 20 percent of the actual cost, it is the health care provider's obligation then not to send a bill that is represented on 20 percent of some fictitious price, he's got to look at what he has actually paid and send a bill based on 20 percent of what he really paid for the drug. Otherwise he is in violation. That is pretty stiff, but what is wrong logically with that

if at the same time we are making the proper adjustments for practice reimbursement to the physician?

Mr. SCULLY. Nothing. It seems logical, and I think the question from Mr. Brown was can we do it now administratively and I don't think we can.

Chairman TAUZIN. Also doing it administratively without correcting the reimbursement on the fund is disjointed. I understand that. There is a $177 million hit for health care providers. But the fairness of asking a Medicare patient to pay 20 percent of a price that is totally fictitious, way in excess of what the physician actually bought that drug for, seems to me to be absolutely insane. It contradicts what we did in the Medicare program, which was literally to provide a co-pay requirement on the patient that was supposed to be one-fifth of the actual cost and, because of this crazy system of average wholesale pricing, can run as high as 500 percent of the cost. And I mean not only is it unfair basically to think about that but think about it in terms of if you happen to be the wrong patient, you happen to need that drug that is 500 percent as opposed to another patient that is paying closer to the real 20 percent. There is an inequity in the requirements under the Medicare system depending upon how unlucky you are, what disease you have got, what drug you need to help you.

I would think that we should all look at expediting a cure for that particular problem. Perhaps we can do that sooner than later.

Mr. SCULLY. We would love it. We are totally with you. I think the best thing about this hearing was for the health care policy wonks in the world, many on your committee, this issue has been around about 10 years and I never heard this thorough a discussion on it, and usually what happens is somebody tries to cut a rate and somebody screams that patients are going to be hurt, which is frequently not the case, and we are legislatively prohibited from fixing it.

Chairman TAUZIN. You said the right thing, legislatively prohibited from fixing it, and that can't stand any longer. It is our obligation right here to fix it. We have allowed this to exist too long, as we thoroughly understand it, as we understand its pernicious effects upon the health care system, and particularly upon the very people it is designed to help, we have got to fix it, and if there are legislative impediments to your fixing it, we need to take them out of the way.

Thank you very much. I will recognize Mr. Ganske for 5 minutes.

Mr. GANSKE. Thank you, Mr. Chairman. I want to follow up on your line of questioning. It seems to me that the problem with instituting a limit on the co-pay to the actual cost without doing the rest is just what we have been talking about multiple times this morning; that is, that you are not taking into account the overhead involved with the administration, with the storage, with the ordering, with the time involved for personnel and things like that, and so I think that that issue of the co-pay is corrected when you actually have the inaccurate index of the cost, I mean of the drug, whether it's an AVP, or whatever letters you want to use.

Mr. Scully, I want to go to this issue of the AMP data. This is a quote from the IG report. "This option would require legislation to allow Medicare access to AMP data. Prior to this option being

implemented, it would be useful to clarify or refine certain definitions. We also believe that an initial intensive effort should be made to audit AMP data." We don't want to just substitute some letters. We need to have some accuracy. Do you have any idea of what the definitions that we would need to address to clarify and define what the IG is talking about in terms of AMP?

Mr. SCULLY. That is considerably lower and I think it generally works. It is confined to Medicaid by statute, and our Medicaid staff has access to what the Medicare staff does not. It is audited. If we use it for a broader chunk of the market and used it for Medicare as well as Medicaid, obviously incentives for people reporting their prices would—we'd have to probably audit more carefully, as the IG said, and be much more thorough in making sure the prices are accurate. But the idea of AMP, which is similar to an average sales price concept, is to actually find out what the manufacturer sells it to all customers in the country in any particular year and then come back and make it that that is the average price that we pay. I think the data is there now to make it work, and it is certainly the best measure to make it work.

The problem is if you go out to many areas of the country where physicians and oncologists may actually have to pay more for it, there may be places where somebody can't get access to that. That was the argument about paying 85 percent of AMP back in 1991. If a physician in Iowa, for instance, couldn't get access to the drug for that price, he might never get it. So some have suggested that just consensually what we would do is allow the companies charge whatever they want, but then at the end of the year come back and reconcile, similar to what Medicaid does now, and say you sold us a million units of the drug times whatever the average manufacturer's average sales price is, you owe us the difference. That way you keep access to the physician out there buying in the market while actually recovering from the manufacturer.

The problem with that, which is what I was trying to get to Mr. Brown, is then what do you do up front as far as charging 20 percent of what, the inflated AMP or the real end of the year price the government ends up paying, and that is difficult.

All things I think we can talk about fixing legislatively, but it is a complicated problem to make sure we don't overpay, but that we also don't shut off access to physicians who may not in some parts of the country be able to get access to the drugs. So it is a complicated problem. I think we can fix it, but I have only been looking at it intensively the last 2 or 3 days and I can't tell you all the answers yet.

Mr. GANSKE. Can this committee expect from the administration and from you and CMS some specific suggestions for instance on the, quote, clarification and refinement of certain definitions, unquote, that we would need to do legislatively if we were looking at going the AMP route?

Mr. SCULLY. Sure. Obviously we are hoping, and if we are only here for a month to spend a lot of time on legislative issues, we certainly have a lot of suggestions in this area. We have already spent a lot of time talking to committee staff.

Mr. GANSKE. We are dealing with 24 drugs; is that right?

Mr. SCULLY. I think the bulk of the 24 is about 90 percent.

Mr. GANSKE. It would seem to me that we ought to be able to get a handle through sampling of real invoices on 24 drugs, what the real average wholesale price, or the AMP, should be to address this.

Mr. SCULLY. Actually the companies that report AMP are required to tell us what their average price was to all their buyers in the course of the year in any category, and we audit that. So it should be a pretty accurate number. We just can't use it right now for Medicare.

Mr. GANSKE. How do you audit that?

Mr. SCULLY. I believe the IG—the Medicaid actually goes into the companies and audits——

Mr. GANSKE. It goes into the company books and then checks——

Mr. SCULLY. That is right. It is the OIG who actually does it for us.

Mr. GANSKE. And then checks back with the customers of those companies to see whether that in fact——

Mr. SCULLY. Yeah. The only potential flaw I have seen is that some drugs, once you put Medicare and Medicaid together, it is—you know, to figure out what the rest of the market is paying and piggyback on that. A few of these drugs, the market is mostly Medicare and Medicaid. So it is a little difficult to figure out the prices if the non-Medicaid/Medicare market is 10 percent. That is the only flaw I have seen so far in looking at it.

Mr. GANSKE. We both know it has been difficult to get accurate indices of practice expense. There has been a lot of controversy in those areas. If we are talking about changing this reimbursement, what will be the process to get an accurate assessment from these medical specialties that will be affected?

Mr. SCULLY. I believe, and again I hope somebody will jump in here if I am wrong, all the specialties already have the ability to put in their own surveys. The oncologists could have put in their own practice survey and did not. The data that we had on oncology combined their actual drug costs so close to their practice expense costs that we made the decision, which I believe GAO agreed with, that we couldn't use that data. So we used the average physician's practice expense. I think that was defensible because arguably the physicians are already, from what we have heard today, being overcompensated on the drug side; so using the average physicians practice expense is reasonable.

If you in fact reduce the AVP and you made the judgment that we should go back in and do a survey of oncology data or have them submit their own, we believe that would result in their practice expenses going up, but right now the practice expense component for oncologists is the actual average practice expense for all physicians because we don't use oncology specific data.

Mr. GANSKE. We have testimony today from Dr. Norton to the effect that the Medicare payment for services for administration may be one quarter what the actual costs are. Do you have a feeling for that?

Mr. SCULLY. I have not, to be honest with you, looked at that level of detail. Totally independent of each other, both the GAO and our staff looked at this number and came up with a remarkably close initial determination. So I am happy to go back and

spend time with the oncologists discussing it, I am sure I will if you are looking at legislation, but I have yet to find a physician group that was not unhappy with their practice expense allocation. I think that is the nature of the beast.

Mr. GANSKE. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentleman, Mr. Norwood, for 5 minutes.

Mr. NORWOOD. I thank the chairman and I only have one question. I am curious to see what Mr. Scully has to say. You implied earlier there seems to have been a problem at least as far as 10 years back, that HCFA has been concerned and has raised questions about this for a long time, however generally when you raised questions very loud and stuck your head up very far, Congress pounced on you. Is that where we have been?

Mr. SCULLY. That is fair, but sometimes in fairness it is Congress, sometimes it is, you know, groups coming in and screaming within your own administration, whether it is—Gail Walinsky was the first person to get involved in this in 1991 and I was in the White House then, and I remember not knowing very much about it but I remember we got a lot of heat for it. I think the level of understanding and interest this year is an all-time high and that is positive. I think generally whether it is Congress or just people complaining about it, when you have talk about cutting, the groups that are affected are always upset, and generally they are upset because in the past the issue has generally been lowering reimbursements without being sensitive to the fact that maybe there is an unfortunate—but reality is cautious. As I mentioned, I know for ESRD clinics, they argue that their rates are too low as well and that they rely on AVP transfers and cost shifts. Generally the answer in the past has been cut the rates and don't be sensitive to the other side, which does not seem to be the case this year.

Mr. NORWOOD. My question, Mr. Scully, though, is since this has been a problem for a long time, I am a little bit surprised that why would not CMS or GAO or somebody be coming to this hearing today with a solution?

Mr. SCULLY. It is not an easy solution. I spent 4 hours the other day with probably 10 people at CMS that have worked on this for the longest time and went around with the options I put in front of you today briefly, and I am not sure we have a consensus in our agency about what is right. We are going to have to pick one. I think it will be a hybrid of a bunch of these, but I am not sure that you could find a consensus solution anywhere. I would be happy to sit down with the committee and give you my opinions.

Mr. NORWOOD. I was struck by the different options that you sort of threw at us pretty quickly, and I guess is this not solvable?

Mr. SCULLY. I think it is very solvable. I think there are shortcomings to every solution and some benefits to every solution, and some people are not troubled by just saying let us pay the Federal Supply Schedule. I don't think that that—which the VA pays, which the Coast Guard and other agencies pay. I think that probably causes significant access problems for some physicians in some places. So there are pros and cons to every option and, if you would like, I would be happy to share my staff paper on the pros and cons with you.

Mr. NORWOOD. I think my feeling is this, the Energy and Commerce Committee is going to do something about this one which way or the other and it certainly should be and is our responsibility, but I also think it is the responsibility of the Federal agency to also come up with a solution. It doesn't necessarily mean we will adopt that. It doesn't mean that that will be the final solution. But I think you need to lead your organization to the plate, get up to bat, let us hear what you want to do. And at the same time our chairman, all of them along the line are going to be doing the same thing. But I am not sure I feel like we, the members of this committee have—should have had the experience dealing with this problem for 10 years at the same level as your agency has had experience dealing with this problem, and I am suggesting that you have some responsibility in my mind to not give us a dart board and hope we hit the right one. Come in here and say what you want to do.

Mr. SCULLY. Mr. Norwood, I almost have never been accused of not having strong opinions about things for better or worse. The problem is that we are legislatively prohibited at least until today from considering this. So there is not an administration position. As I have——

Mr. NORWOOD. Are you prohibited from coming up with a solution?

Mr. SCULLY. No. But the fact is we have an administration with a White House and the Secretary—I have talked to the Secretary a little bit about it. I am not sure that the White House is aware of this. I can't state the administration's position publicly today. I have opinions. I will talk in the next week or so with people in the administration, and I have no doubt we will have a strongly held administration position. I am just not in a position today to go any further than I have.

Mr. NORWOOD. I didn't expect today for you to come up with a solution. I expected for you to turn to some of that staff that has been over there over the last 10 years and I presume are working on this. At some point in time the agency itself should make a recommendation as to how they think we would best solve this problem and hopefully this committee and the subcommittees and full committee will go along with that, maybe alter that, maybe change that. But you need to have a position.

Mr. SCULLY. I hope we can come up with a joint position with the committee, and we will give you lots of technical input, and whatever the committee decides I have a feeling will be the administration's position as well and we will hopefully do it together aggressively and on a bipartisan basis.

Mr. NORWOOD. Thank you, Mr. Chairman.

Mr. GREENWOOD. The time for the gentleman has expired. Let me comment that in fairness to everyone, we have all been on hold until the GAO study came out, which has been released today, and we now feel that we have a solid footing upon which to build our solution. The wholesale acquisition costs will almost certainly be the basis for the new reimbursement rates, will take care of the oncologists and others based on the data that we have now, and I think we will be prepared to work with CMS over the next couple

of weeks and have a firm detailed legislative product in short order.

Mr. Scully, thank you for your excellent testimony. Thank you for your patience and you are excused. Look forward to working with you.

I call now the third and final panel: Dr. Larry Norton, President of the American Society of Clinical Oncologists; Mr. Kevin Martyn, Executive Director of Care for Life; Mr. Thomas Connaughton, President of American Association of Homecare; and Dr. Ezekiel Emanuel, Chief, Clinical Bioethics Department, Warren G. National Magnuson Clinical Center, National Institutes of Health. Welcome. We thank you for your patience in waiting all morning and all afternoon to testify, but we are glad to have you with us.

As you probably heard me say to the previous witnesses, this is a joint committee hearing between the Health Subcommittee as well as the Oversight and Investigation Subcommittee, and when the Oversight and Investigation Subcommittee is involved, we take testimony under oath. Do any of you object to providing your testimony under oath?

Seeing no such objection, I would inform you that you are entitled under the rules of this committee and under the rules of the House to be represented by counsel. Do any of you desire to be represented by counsel? Seeing no such desire, if you will rise I will give you the oath.

[Witnesses Sworn.]

Mr. GREENWOOD. Thank you. You are each under oath now, and we will begin with you, Dr. Norton. You are recognized for 5 minutes for your testimony. Make sure your button is——

Dr. NORTON. Am I on?

Mr. GREENWOOD. Yes.

TESTIMONY OF LARRY NORTON, PRESIDENT, AMERICAN SOCIETY OF CLINICAL ONCOLOGISTS; KEVIN MARTYN, EXECUTIVE DIRECTOR, CARE FOR LIFE; THOMAS A. CONNAUGHTON, PRESIDENT, AMERICAN ASSOCIATION OF HOMECARE; JoANN LAMPHERE, LEWIN GROUP; AND EZEKIEL EMANUEL, CHIEF, CLINICAL BIOETHICS DEPARTMENT, WARREN G. MAGNUSON CLINICAL CENTER, NATIONAL INSTITUTES OF HEALTH

Mr. NORTON. Hi, I am Larry Norton. Pleasure to be here. I am a physician, an oncologist, and this year I am President of the American Society of Clinical Oncology. I am also a New Yorker. So I don't have to belabor this. It has been a really rough couple of weeks, but I am delighted that you are having this hearing at this time because this is a topic of great urgency and importance to cancer doctors and cancer therapists in the United States.

My organization represents cancer therapists, physicians, nurses, patient advocates, and others who take care of people with cancer and also people doing clinical research. I currently am also the head of Medical Oncology, called the Division of Solid Tumor Oncology, at Memorial Sloan-Kettering Cancer Center in New York. I have dedicated my life almost 30 years to cancer treatments, largely chemotherapy treatments and largely for breast cancer, and it is of critical importance to me and my colleagues that the thera-

pies that we develop that have been improving the life-span, cure rates, and the quality of life for our patients, that this can actually be delivered to our patients. So this is an issue of really critical importance to us.

We agree that the system has to be fixed. We think that the payments for the drugs have to be aligned more closely to the actual costs, but we also think that the payments for the services that are rendered in the administration of these therapies have to be made more realistic, and we think this has to be done very carefully, has to be done jointly, or else we see the possibility of severe disruption to the care of our Medicare patients, and for this reason I underscore the urgency of this particular activity.

We have made really significant progress in cancer therapy over the years. Many therapies that developed initially in the inpatient setting can now be given in the outpatient setting safely, the advances in treatment of nausea, advances in treatment of low blood cell counts, and many other improvements as well as the therapies themselves that have made such a difference. Therapies that used to require inpatient administration not that long ago can now be given—complex skill requiring therapies can now be given routinely in doctors' offices and this is more than just a convenience. This is an essential contributor to the quality of life as well as the length of life for our patients. We want to be sure whatever happens, whatever you decide to do and however you go about this, that the net result must be that doctors will be able to give chemotherapy to their patients in their offices. We calculate that about 70 percent of chemotherapy treatments are given in doctors' offices right now. If the payments, the total payments, for these therapies are not adequate, doctors will not be able to afford to do it. Some people said then they will refer them to hospitals or cancer centers. Cancer centers could be very far away from the patient in many parts of the country, and I don't know any cancer center that can handle a large influx of patients in this particular setting, certainly not my own.

I am in charge of the Outpatient Breast Center of Memorial Sloan-Kettering Cancer Center and if we had a sudden influx of cancer patients with—breast cancer patients in the community for us to treat, we just couldn't handle it. So I don't think that is really a solution. Therefore, whatever we do if we don't do it carefully, we could see a real massive disruption in the system.

So much of the discussion today is concerned with reimbursement for the drugs that are administered. We think the system does need to be fixed. There is no question about that, but I want to emphasize there has to be a simultaneous change in the reimbursement for the physician administering the therapy. Right now there is a gross underpayment, as everybody has acknowledged, and that the payments for drugs have to some degree compensated for that.

If we don't reform the whole system at the same time, things are going to get thrown out of whack. It is like a car with a bad axle and a bad tire rim. You fix one. If you don't fix the other, you can't drive the car. I think that's exactly the situation that we find ourselves in. Medicare has determined this and I haven't heard anybody say this is not the case.

I have a quote here that says Medicare payments for services related to provision of chemotherapy drugs are inadequate. We agree with this assessment. Actually our own calculations are that Medicare now pays for less than a quarter of the actual costs to the doctor in administering principal chemotherapy treatments. We think that part of this is the way that the—the methodology for calculating the payment amounts for services that do cost the doctor a lot but not directly furnished by the patient. In 1998, when Medicare adopted this particular methodology, it called its approach an interim approach, but it still hasn't been revised.

We also feel there has to be a new type of Medicare payment for services that are directly related to administration of chemotherapy, directly related but right now not covered by any explicit reimbursement. There are many services that oncologists and their staff provide that are absolutely essential for taking care of these patients, such as social work, such as nutritional counseling, such as psychological support, and these are not really being covered. A big difference between oncology and the specialties is in other specialties an occasional patient has this requirement, for the oncologist essentially all the patients, and this has to be provided as an intrinsic part of the procedure.

We believe that the costs of the chemotherapy administration has to be covered, but if it's just covered, then there is not going to be sufficient funds to provide these other critical services, and this has to be taken into account.

Now, concerning the payment for the drugs themselves, we agree with pretty much everything that's been said. The AWP really overstates by varying amounts the amount, and clearly this is a big problem. We think this is not right. Mr. Chairman, you use the word "outrageous," and I think it is a well chosen word. We actually have—we have proposals on the table. We have proposed a solution. It is in the form a white paper, and I would like to request that it be included in the record.

Mr. GREENWOOD. The document will be included in the record.

Mr. NORTON. Thank you. And in that we talk about the surveys of the drug sellers to determine market prices or a correction in the actual published prices, and that's really what should be used to determine the reimbursement. But fundamentally we believe that if the cost is not covered, it's going to be impossible for the doctors to administer the therapy. Our job is to take the best possible care of our patients with cancer. It's a very hard job. I want to emphasize that. It's not just the intellectual challenges. The field is changing all the time. It's the psychological challenges, the emotional challenges, the spiritual challenges and I've got to tell you the hours are just unbelievable.

We want to provide the very best care for our patients. We think that we need to have accurate reimbursements so we can do it financially. Anything that we do that is going to throw the system out of whack is going to hurt us from doing that. We are totally dedicated to quality cancer care and we want to work with Congress to make sure that the care we're now administering is provided at the highest possible quality level.

Thank you very much.

[The prepared statement of Larry Norton follows:]

PREPARED STATEMENT OF LARRY NORTON, PRESIDENT, AMERICAN SOCIETY OF CLINICAL ONCOLOGY

My name is Larry Norton, President of the American Society of Clinical Oncology (ASCO). ASCO is the national organization representing physicians who specialize in clinical research and the treatment of cancer. ASCO has over 17,000 members, including nonphysician healthcare professionals and cancer specialists located abroad.

I appreciate the opportunity to appear before the Committee today to present ASCO's views on the important subject of Medicare payment for the drugs and related services furnished in outpatient cancer treatment. ASCO agrees that Medicare payments for drugs and related services should be restructured to more closely align the payment amounts with the cost of providing cancer care. Payments for drugs should be reduced while payments for the related services should be increased. It is imperative that this be done carefully, however, to insure that delivery of treatment to Medicare beneficiaries is not disrupted.

NEED TO PRESERVE OUTPATIENT CHEMOTHERAPY

I am Head of the Division of Solid Tumor Oncology at Memorial Sloan-Kettering Cancer Center in New York. As a specialist in the treatment of breast cancer, I am very familiar with chemotherapy and its importance in cancer treatment. Any reform of the Medicare payment system for chemotherapy must insure that cancer patients can continue to receive what they need to fight their disease. Chemotherapy is central to modern cancer treatment and is likely to be even more important in the coming years. Chemotherapy treatment was once considered far worse than the disease, requiring extensive hospital stays. Now, with better drugs to control side effects, patients can receive treatments in outpatient settings most convenient for them—and for their families. This is usually in physician offices.

In restructuring the Medicare payment system for chemotherapy, the net result must be aggregate payment amounts that enable physicians to continue offering office-based chemotherapy. It has been estimated that 70% or more of chemotherapy treatments are furnished in physician offices. If Medicare payments are not adequate to cover the costs of this service, physicians will be forced to have chemotherapy delivered in some other setting. It is far from clear, however, whether hospital outpatient departments have the capacity or the resources to handle a large inflow of chemotherapy patients. Any significant reduction in office-based chemotherapy could therefore result in a massive disruption in the care of Medicare patients with cancer.

PAYMENTS FOR DRUG-RELATED SERVICES

As I stated above, ASCO supports a reduction in the Medicare payments for drugs. Before discussing that aspect, however, I want to speak first about the simultaneous change that must be made to insure that Medicare cancer patients will still be able to obtain chemotherapy treatment after the drug payments have been reduced. Under the current reimbursement system, the payments for drugs compensate for the underpayment or lack of payment for the related services, and all parts of the system must therefore be reformed at the same time.

In the 1970s, there were few drug treatments available for cancer and, as I mentioned earlier, those that were available were generally administered to hospital inpatients. The few types of chemotherapy that were first furnished in the office setting were relatively simple, but they established the basis for the low Medicare payment levels for chemotherapy administration services that continue to exist today. There has been no major revision, even though the complexity of chemotherapy furnished in the outpatient setting has increased enormously. This problem was noted by Congress as early as 1987, when the Omnibus Budget and Reconciliation Act required the Department of Health and Human Services to conduct a study of the costs of furnishing chemotherapy in the office and assess whether payments are adequate. Unfortunately, this study was never conducted.

Last year, however, the Health Care Financing Administration, now the Centers for Medicare & Medicaid Services (CMS), reviewed the matter and wrote Congress that "Medicare payments for services related to the provision of chemotherapy drugs . . . are inadequate."

The inadequacy of the Medicare payment amounts is illustrated by the costs of one of the principal services. Under the physician fee schedule, the current Medicare payment level for the first hour of a chemotherapy infusion (CPT 96410) averages about $62. The cost of the supplies and equipment used in this procedure are estimated to be about $29, based on the 1994-95 prices used by CMS for these esti-

mates. The salary and benefits of the oncology certified nurses who furnish chemotherapy are currently estimated by CMS to average about $35 an hour, and the total nurse time involved in furnishing an hour of infusion is estimated at about two hours. Among other elements, this work includes reviewing the patient's medical history, verifying the drug orders, preparing the drug, educating the patient, assembling the necessary supplies, administering the drug, documenting the procedure, and follow-up phone calls.

Thus, the costs of the supplies, equipment, and nurse time for an infusion by themselves significantly exceed the Medicare payment amount. Moreover, there is nothing in the Medicare payment to cover the other costs of the office, including the administrative staff and the overhead, which CMS, using American Medical Association data, estimates to be about two-thirds of a physician's costs. The Medicare payment amount for chemotherapy services are far less than the costs incurred to furnish the services. ASCO estimates that Medicare pays less than one-fourth of the total costs of the principal chemotherapy procedures.

ASCO believes that this underpayment results at least in part because of the way in which the methodology for the Medicare physician fee schedule sets payment amounts for services that may represent significant expense to a practice but are not directly furnished by the physician. Chemotherapy is one example. At the time CMS adopted this methodology in 1998, it characterized its approach as "interim" but the methodology has not yet been revised.

ASCO believes that the payment amounts for services of this kind—those that do not have a physician work component—should be based on information about the costs of providing those services, and not on the current "top-down" methodology that is used in general to set payment amounts. Although it would be desirable to collect new cost data, any restructuring in the near future must depend on information that currently exists or can be promptly developed. Consequently, ASCO recommends use of the data on costs that was initially developed by the Clinical Practice Expert Panels and has subsequently undergone review in the American Medical Association refinement process and analysis by CMS. Medicare should pay the full direct and indirect costs of chemotherapy services as estimated in that process.

There should also be a new type of Medicare payment for services that are related to chemotherapy but are not part of the chemotherapy procedure itself. Oncologists and their professional staffs typically furnish a variety of services to cancer patients for which there is no explicit reimbursement. These services include the extensive support that seriously ill cancer patients frequently require, including social worker services, psychosocial services, and nutrition counseling. Social worker services encompass a variety of services intended to help patients carry out their therapy, such as help with insurance, arranging transportation to treatment, and filling prescriptions. Psychosocial support includes services such as counseling patients on their activities of daily living, support groups that meet in the physician's office, and grief counseling. In addition, physicians treating cancer patients perform an extraordinarily high amount of work outside the patient's presence, including family counseling, telephone calls, arranging for entry into clinical trials, and so forth. While other types of physician specialists may provide such services to occasional patients, oncologists and their staffs typically provide these services to the bulk of their entire patient load. If the Medicare payments for the drugs and drug administration are aligned closely with their costs, there will not be sufficient funds available to continue these services, which are so important to the seriously ill cancer patient population. Medicare patients need to continue to receive these services to deal with their disease, and the services should not be cut off to save money.

PAYMENTS FOR DRUGS

Finally, let me turn to the Medicare payments for the drugs themselves. The current Medicare payment amount for covered drugs is based on 95% of published average wholesale price (AWP). As is widely known, published AWP overstates, by a varying amount, the prices at which drugs can actually be purchased. This circumstance does not necessarily make AWP useless, however, and AWP is widely used by public and private insurance programs in their reimbursement methods for drugs that are dispensed by pharmacies or administered in physician offices.

In recent years, the difference between AWP and actual prices for some drugs has become very large. This situation typically occurs for multiple-source drugs or drugs with close competitors, where competition forces down the actual price even though the list price, on which AWP is based, remains high. The large discrepancy between price and reimbursement amount for some drugs is not an appropriate situation.

As part of restructuring the Medicare payment system, ASCO recommends one of two approaches to revising the payments for drugs. First, Medicare could deter-

mine the market prices of each drug. Instead of using AWP, the law could require drug wholesalers to report to a Medicare contractor the prices at which they sold each Medicare-covered drug, considering all discounts, and the quantity sold at that price. The contractor could then compile those reports into a picture of the range of market prices for each drug and set a Medicare payment level accordingly.

If this market approach is adopted, ASCO believes that a number of features should be included to insure that the survey results in an appropriate payment level:

- The price reports should be frequent so that they reflect changing market conditions. ASCO recommends that the wholesalers submit reports every month and that the contractor process the data promptly so that it can be used for reimbursement purposes in the second following month. For example, prices of drugs sold in January would be used to set the payment amounts for March.
- Since there will be a variation in the prices, the Medicare payment level for each drug should be set at an amount that will cover the prices actually paid by the vast majority of physicians. ASCO recommends the 95th percentile. Prices actually paid may vary greatly because physicians in larger groups are able to negotiate lower prices based on their volume purchases. It would be extremely unfair to pay based on the median price or some similar price because that would systematically discriminate against physicians who are unable to negotiate lower prices. Oncologists who are routinely reimbursed less than what they pay for a drug would be unable to continue furnishing drugs to their patients.
- The payment methodology should be flexible enough to take known manufacturer price increases into account immediately. For example, if data on wholesale prices is collected during January for use in March, but the manufacturer raises the price of a drug by 5% on February 1, that should be taken into account in setting the March payment amounts.
- There should be an add-on amount to reflect certain costs associated with use of the drug. These include costs such as spillage, wastage, the opportunity cost of the capital tied up in drug inventory, procurement and storage costs, and unpaid patient coinsurance (bad debt). Although Medicare Part B does not ordinarily cover bad debt, bad debt here represents an out-of-pocket loss to the physician and should be treated specially. The various components of these extra costs are difficult to estimate, so ASCO recommends a flat 10% add-on to cover them.
- Sometimes physicians will encounter especially high prices for drugs, such as if they have to purchase a drug from a pharmacy in an emergency. The system should always allow a physician to be reimbursed for the actual acquisition cost by submitting documentation as to the purchase price.
- In states that impose a sales or gross receipts tax on physician-administered drugs, Medicare should also cover that amount so as to keep the physician financially whole.

An alternative approach to using a survey of market prices would be to make the published prices used by Medicare more accurate. The main concern expressed about the published prices has been the particularly large differences between the published prices and actual prices for some drugs. The law could be changed to require manufacturers to submit accurate prices to the publishers. This approach would have the advantage of not requiring a government contractor to compile data.

ASCO could support either of these approaches and we would be happy to work with Congress to develop the details of an appropriate methodology. Our concern is only that the resulting Medicare payment must be adequate to cover the full costs incurred by oncologists. Oncologists pay varying amounts for drugs, with large practices and entities able to obtain volume discounts not available to everyone. The methodology adopted must be adequate to insure that all oncology practices, regardless of size, obtain full reimbursement of all their drug-related costs.

HOSPITAL OUTPATIENT DEPARTMENTS

The Medicare statute ties payments under the hospital outpatient prospective payment system to AWP by paying for drugs used in cancer therapy based on 95% of AWP for a two to three year transitional period. As the payment methodology for drugs furnished in physician offices is revised, it is important that possible effects on payments for services in hospital outpatient departments be kept in mind. Hospital outpatient departments are an essential part of the delivery system for cancer care, and Medicare payments must be adequate to support their continued operation.

CONCLUSION

In summary, ASCO supports restructuring Medicare payments for chemotherapy related services by reducing the payments for drugs and appropriately increasing the payments for related services. It is essential that the cumulative payments after this restructuring fully cover the costs of the items and services that oncologists furnish to cancer patients. If their costs are not covered, oncologists will be unable to continue furnishing chemotherapy in their offices, and the result could be extreme disruption of the cancer care delivery system.

Oncologists have dedicated their professional lives to treating patients with cancer, and our only objective here is to insure that our patients can continue to receive the therapy and services that they need in the setting that is most convenient and accessible. We believe that Medicare payments can be restructured without adverse consequences if our recommendations are adopted, and we look forward to continued work with the Congress toward that end.

Mr. GREENWOOD. Thank you very much, Dr. Norton. We appreciate your testimony. And now, Mr. Martyn, you are recognized for 5 minutes.

TESTIMONY OF KEVIN MARTYN

Mr. MARTYN. Thank you, Mr. Chairman and members of the committee, for allowing me the opportunity to testify today. This hearing addresses a subject that has a potential to impact directly the quality of care that our patients receive, and I would ask that the prepared testimony that I have submitted be included for the record.

I am the Executive Director of Care for Life, which is a pharmacy and home health care provider. We provide blood clotting factor products and related services and support the persons diagnosed with hemophilia who self-infuse at home. The ability of our patients to treat their conditions by self-infusing at home instead of being treated in a hospital emergency room or treatment center allows individuals suffering from this condition to lead more normal, healthy and productive lives. We believe that home infusion also saves the government money.

Mr. Chairman, as a health care provider who has served the hemophilia community for many years, I very much appreciate this committee's concerns over the high cost of medications and providing care. I am aware that there has been considerable criticism for paying providers based on the average wholesale price, and I would agree that the AWP may not be the right mechanism for all parts of the Medicare program.

Having said that, Care for Life experienced firsthand last year what happened when AWP was reduced without adequate consideration for the impact on patient care. When AWP was suddenly lowered for blood clotting products, my company faced the difficult task of telling some patients that we could no longer provide care. We delayed this decision in every case for several months while operating at a loss, but as a business we cannot do that for long. Fortunately, in all but a handful of cases the State Medicaid directors decided to switch back to the previous accepted AWP levels or made modifications to their reimbursement level accordingly, and we were able to continue to provide care.

At least with respect to disease that we treat, the current payment mechanism has resulted in good care at a fair price. I would like to describe briefly how we arrived at this system, the system that at least for hemophilia works quite well.

Mr. Chairman, many years ago the primary way for hemophiliacs to receive care was to go to a hospital emergency room. There the doctor would examine them and continue to infuse and to notify the patient that they were having a bleeding episode, and of course in this diseased state many patients are aware previous to that of that situation. They would then be admitted, given an IV, or infusion, and then released.

Eventually policymakers, the health care industry, and the hemophilia community realized it would be just as effective medically to encourage a shift to self-infusion at home and that doing so would in many cases be better for patients. Home infusion is better because patients begin to infuse sooner, which stops the bleeding faster, thereby decreasing likelihood of greater damage. In addition, Medicare and Medicaid pay dramatically less than if a patient had to go to the hospital for treatment.

The idea worked and today Medicare and Medicaid enjoy very significant cost savings from home infusion. For example, according to a study published in the Journal of Care Management in June 1998, treating a minor bleeding incident at home cost $4,400 less than treating the same incident at the hospital. If only one-third of the hemophilia population experiences 10 minor bleeds for which they are needlessly required to visit the emergency room for treatment, the additional cost would be upward of $44,000 per person for minor incidents per annum. Multiplying that by 8,000, roughly one-third of the hemophilia population, that total cost of government could be as high as an additional $352 million annually. For severe hemophiliacs the additional cost of emergency room treatment would be much higher, more than $100,000 per year. These additional costs do not include those costs associated with treating the increased physical injuries hemophiliacs suffer from the delay involved in having to make a trip to the emergency room.

In addition to the health benefits, self-infusion at home reduces administrative cost. For the service we provide the Federal Medicare program only makes one payment under Part B. With the reimbursement based on AWP, Care for Life performs all the services associated with providing the clotting factor. These services include having pharmacists on staff to dispense and track drug interactions, nurses, administrative personnel, shipping, storage, training, supplies, and the cost of advancing the money used for purchasing the clotting factor. Care for Life, like many of the providers upon which Medicare relies, is a for-profit enterprise. Just like any other business we must make a reasonable profit margin or investors will put their money elsewhere. After taxes we make roughly 7 percent, which I believe is a reasonable return.

If the reimbursement mechanism were changed so that the reimbursement was substantially decreased, providers like Care for Life would be forced to send patients back to the hospital. That in turn would ultimately lead to increased costs to the Medicare and Medicaid programs and the decrease in quality of care received by individuals with hemophilia. It is an outcome that I am confident this committee will work to avoid.

Again, I thank you for holding this hearing and for giving me the opportunity to testify. I share in your concerns, and I applaud your

efforts to develop a reasonable approach to Medicare reimbursement, and I will welcome any questions you might have.

[The prepared statement of Kevin Martyn follows:]

PREPARED STATEMENT OF KEVIN MARTYN, PRESIDENT, CARE FOR LIFE

Chairman Bilirakis, Chairman Greenwood, Members of the Committee, good morning. My name is Kevin Martyn. I would like to thank you for the opportunity to testify today. This hearing addresses a subject that has the potential to impact directly the quality of care that our patients receive. I would ask that the prepared testimony that I have submitted be included in the record.

I am the President of Care For Life. Care For Life is a pharmacy and home health care provider. We provide blood clotting factor products and all related services and support to persons with hemophilia who self-infuse at home. The ability of patients to treat their condition by self-infusing at home—instead of being treated in a hospital emergency room or treatment center—allows individuals suffering from this condition to lead more normal, healthy, and productive lives. Home infusion also saves the government money.

Mr. Chairman, as a health care provider who has served the hemophilia community for many years, I very much appreciate this Committee's concerns over the high cost of providing care. I am aware that there has been considerable criticism of paying providers based on the average wholesale price, or AWP, and I would agree that AWP may not be the right mechanism for all parts of the Medicare program. Having said that, Care For Life experienced first hand last year what happened when AWP was reduced without adequate consideration for the impact on patient care. When AWP was suddenly lowered for blood clotting products, my company faced the difficult task of telling some patients that we could no longer provide care. We delayed this decision in every case by several months by operating at a loss. But as a business we could not do that for long. Fortunately, in all but a handful of cases the state Medicaid directors decided to switch back to the old AWP levels, and we were able to continue to provide care. At least with respect to the disease that we treat, the current payment mechanism has resulted in good care at a fair price. I would like to describe very briefly how we arrived at this system—a system that, at least for hemophilia, works quite well.

Mr. Chairman, many years ago the primary way that hemophiliacs received care when they were having a bleeding episode was to go to a hospital emergency room. There, a doctor would examine them and tell them what they already knew: they were having a bleeding episode and needed an infusion of clotting factor to stop the bleed. The patient would be admitted, hooked up to an IV, given an infusion, then released. Eventually, policymakers, the health care industry, and the hemophilia community realized that it would be just as effective medically to encourage a shift to self-infusion at home, and that doing so would in many cases be better for patients. Home infusion is better because patients begin to infuse sooner, which stops the bleeding faster, thereby decreasing the likelihood of greater damage. In addition, Medicare and Medicaid pay dramatically less than if the patient had to go to the hospital for treatment.

The idea worked, and today Medicare and Medicaid enjoy very significant cost-savings from home infusion. For example, according to a study published in the Journal of Care Management in June of 1998, the cost to the government of treating a minor bleeding episode in an adult male who self-infuses at home is $1,186.

Alternatively, if that patient had to make an emergency room visit to get treatment—for the same minor bleeding episode—the cost to the government would be $5,620. That is a difference of more than $4,400 per incident, again, based on a *minor* bleeding episode.

Light to moderate hemophiliacs may bleed around 12 times per year. Those with severe hemophilia may experience a bleed 52 times per year. The Centers for Disease Control and the national organizations representing the hemophilia community estimate there are 17,000 to 30,000 hemophiliacs in the U.S. The reported numbers vary because not all hemophiliacs seek treatment at treatment centers that report to the CDC.

Accordingly, if only one third (approximately 8,000) of the hemophilia population experiences 10 minor bleeds for which they are needlessly required to visit the emergency room for treatment, the additional cost to the government would be $44,000 per person for minor incidents in that year. The total additional cost to the government would be $352,000,000 annually.

For severe hemophiliacs, the additional cost of emergency room treatment would be much higher, easily more than $100,000 annually per patient. These additional

costs do not begin to address the increased physical injury hemophiliacs suffer from the delay involved in having to make a trip to the emergency room to get treatment or the additional costs involved in treating those increased injuries suffered as a result of the delay in receiving infusion treatments.

In addition to the health benefits, self-infusion at home reduces administrative costs. With respect to providing clotting factors to hemophiliacs, the federal Medicare program only makes one payment under Medicare Part B. Under the statutory formula, the actual payment from Medicare equals 76% of the AWP for the clotting factor used. We get 76% of AWP because the law directs Medicare to pay 80% of the allowable cost, which is statutorily set at 95% of AWP. The provider must collect the other 20% of the 95% allowable cost—the co-pay—from either the patient, private insurance, or the state Medicaid program. In the case of Care For Life, roughly 90% of the time we are successful in collecting some portion of that 20% co-payment.

With the reimbursement based on AWP, Care For Life performs all of the services associated with providing the clotting factor. These services include having pharmacists on staff to dispense and track drug interactions, nurses, administrative personnel, shipping, storage, training, supplies, and the cost of advancing the money used to purchase the clotting factor, to name a few.

Care For Life, like many of the providers upon which the Medicare system relies, is a for-profit enterprise. Just like any other business, we must make a reasonable profit margin, or our investors will put their money elsewhere. After taxes, we are making roughly 7%, which I believe is a reasonable return. It is much less than the margins earned by some of the country's telecommunications companies, car companies, and entertainment companies, but enough so that it makes sense to be in this line of business.

If the reimbursement mechanism were changed so that reimbursement was materially decreased, providers like Care For Life would be forced to send patients back to the hospital. That in turn would ultimately lead to increased cost to the Medicare and Medicaid programs, and a decrease in the quality of care received by individuals with hemophilia. That is an outcome that I am confident that this Committee will work to avoid.

Again, I thank you for holding this hearing and for giving me an opportunity to testify. I share your concerns and I applaud your efforts to develop a reasoned approach to Medicare reimbursement. I welcome any questions that you may have.

Mr. GREENWOOD. Thank you, Mr. Martyn. Mr. Connaughton for 5 minutes.

TESTIMONY OF THOMAS A. CONNAUGHTON

Mr. CONNAUGHTON. Mr. Chairman, I am President of the American Association for Homecare. Our association includes the full spectrum of the home care industry, including providers of inhalation and infusion therapies in the home setting. Drugs provided in these therapies have been relevant to this hearing.

I am accompanied by Dr. JoAnn Lamphere of the Lewin Group. At our request Lewin conducted a survey of companies offering inhalation and infusion therapies across the country to determine the costs of providing those therapies in the home. Dr. Lamphere will report on Lewin's analysis of this survey and after making a few general statements I will defer to her.

I want to highlight that the pharmaceutical products used in inhalation and infusion therapies are not simply oral medications. In the case of respiratory medications these drugs must be utilized in conjunction with nebulizers. Infusion drug therapy involves primarily the administration of the drug into the body through a needle or catheter. These therapies cannot typically be administered without a complex array of services.

There are some fundamental principles that are important to understand regarding home care and Medicare reimbursement for prescription drugs.

First, our members provide these products in the home, which is significantly more cost effective than providing them in an institution.

Second, the work of the home care provider begins with a prescription. The provider must furnish the drug prescribed by the physician and is not engaged in the selection of a particular product.

Third, administering pharmaceuticals in the home setting involves a number of functions and services performed by the home care provider. These services include the preparation of patient specific sterile drugs, comprehensive training of patients and often their families, and clinical monitoring to prevent infections and other potentially life-threatening complications. Trained professionals are on call on a 24-hour basis. In most cases providing these services is more costly than the drug itself, as the Lewin report will underscore.

Fourth, unlike managed care, which pays for a product plus services, the sole reimbursement under Medicare Part B for these products is for the drug itself. The difference between the reimbursement rate and the cost of the drug must cover all the services. Outside of a small dispensing fee for respiratory drugs, there is no fee schedule for our services, unlike the physicians schedule.

Fifth, Medicare coverage for infusion therapies is very limited, and Medicare is losing the advantage of efficiencies provided in the home setting that the private sector is taking advantage of.

Sixth, we have not been able to make a recommendation for replacement of the AWP system, and I am somewhat comforted that there has been a lot of questions from everyone who has come up here. It is very complex and there are so many variables. That is why we advise you to proceed with care. If, however, Congress revises the reimbursement system for Medicare Part B drugs, it should make certain that it provides for reimbursement of all the services and functions involved in providing these therapies in the home setting based on standards that are widely used in private sector. It should further expand the coverage of infusion therapies for Medicare beneficiaries.

H.R. 2750, introduced by Mr. Engel and others earlier this year, addresses these issues in the context of infusion therapy. We believe this approach is equally appropriate for inhalation therapies.

Dr. Lamphere?

[The pepared statement of Thomas A. Connaughton follows:]

PREPARED STATEMENT OF THOMAS A. CONNAUGHTON ON BEHALF OF THE AMERICAN ASSOCIATION FOR HOMECARE

Mr. Chairman, my name is Tom Connaughton. I am President of the American Association for Homecare ("AAHomecare"). Our Association was formed by the merger of three national associations on February 1, 2000. We are the only national association that represents every line of service within the homecare community. Our members include providers and suppliers of home health services, durable medical equipment (DME) services and supplies, infusion and respiratory care services, and rehabilitative and assistive technologies, as well as manufacturers and state associations.

We thank you for the opportunity to discuss the Medicare reimbursement system for pharmaceuticals administered to beneficiaries by homecare providers and suppliers, in particular, home infusion therapies and inhalation therapies administered to respiratory patients. Homecare providers and suppliers save Medicare money by treating patients in the most cost-effective setting—their homes. The savings gen-

erated by treating patients at home can be dramatically cost-effective when compared to the cost of the same therapy administered in an institutional setting.

Joining me is JoAnn Lamphere (Dr.P.H.) of The Lewin Group. At the request of our association, The Lewin Group conducted a survey of providers and suppliers of inhalation and infusion therapies in order to determine the costs associated with these therapies. The Lewin Group has prepared a report analyzing the results of this survey. To our knowledge, it is the most definitive report on the subject to date. Dr. Lamphere will summarize the findings of that report and, of course, a complete copy is attached for your information.

I want to begin by making an important distinction between infusion and inhalation therapies administered to patients in their homes and conventional outpatient drugs such as pills and "patches." The key difference is that pills and patches do not require professional services to administer. An individual can consume a pill or apply a patch himself after obtaining it from a retail or "traditional" pharmacy. In contrast, infusion and inhalation therapies cannot be administered to patients at home without a complex array of professional services. These medications are provided only on the prescription of a physician and as required by regulatory, accrediting and pharmacy licensing bodies, are prepared in high-tech, sterile settings similar to those found in a hospital. These services ensure the safe and effective administration of infusion and inhalation therapy in the home.

As we begin this discussion, it is also important to note that homecare providers and suppliers are not paid separately for these important services. Medicare does not have a separate benefit for these homecare therapies. Infusion and respiratory medications furnished to homecare patients are covered under the Medicare DME benefit. This means that the only items that are explicitly covered and reimbursed are the drugs, the equipment, and the supplies. Unlike other health care professionals, homecare providers and suppliers do not have a mechanism that reimburses the services necessary to administer the drugs in addition to the reimbursement for the drugs. By comparison, the private managed care sector has recognized the tremendous cost-savings associated with homecare and it continues to provide coverage for a growing list of home infusion and inhalation therapies. Moreover, such organizations contract with providers for extended periods of time, guarantee tremendous volume, and structure their contracts with both a fee for the drug and a per diem to assist in covering the providers' costs of services.

INHALATION THERAPY

Inhalation therapy is administered to patients with respiratory disease, including, for example, chronic obstructive pulmonary disease (COPD). COPD is the fourth leading cause of death in the United States, affecting 16 million people.[1] COPD includes a number of chronic respiratory diseases such as emphysema, chronic bronchitis, and asthma. Individuals with COPD have a progressive illness. The disease can be stabilized, but it cannot be cured. Inhalation therapy is used to manage COPD throughout the course of the disease, but in the more advanced stages of COPD, other therapeutic interventions may be required.

Specifically, inhalation therapy is the process through which a drug or a combination of drugs is delivered into the airways and inhaled directly into the lungs via a device called a nebulizer. These drugs may include beta-adrenergic bronchodilators, anticholinergic bronchodilators, mast cell stabilizers, anti-inflammatory steroids, antibiotics, and sputum liquefiers. Patients receiving inhalation therapy at home are monitored by respiratory therapists and highly trained pharmacists. Inhalation therapies reduce acute exacerbations of COPD, saving the Medicare program money in emergency room visits and inpatient stays.

INFUSION DRUG THERAPY

Private sector insurance plans and private managed care plans increasingly have embraced home infusion drug therapy since the 1980's. Antibiotic therapy, chemotherapy, and pain management are among the spectrum of infusion therapies that are now commonly provided to patients in their homes. Currently, there are over twenty different drug therapies being offered in the home and other outpatient settings in the private sector. The private sector plans and payers typically recognize expressly and separately the professional services necessary to provide infusion drug therapy in a safe and effective manner in the home setting.

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[1] See National Institutes of Health, Global Initiative For Chronic Obstructive Pulmonary Disease, April 2001; Agency for Health Care Quality Research Evidence Based Practice Guidelines, Management of Acute Exacerbations of Chronic Obstructive Pulmonary Disease.

Infusion drug therapy involves primarily the administration of the drug into the body through a needle or a catheter. Typically, infusion drug therapy means that a drug is administered intravenously, but it may also apply to situations where drugs are provided through other parenteral (non-oral) routes. Generally, infusion drug therapies are used only when less invasive means of drug administration are clinically unacceptable or less effective. A team of patient service representatives, clinical pharmacists, high tech infusion nurses, and delivery and reimbursement professionals support patients and their caregivers throughout their treatment. These services are inextricably linked to the therapies and are often mandated by accrediting bodies whose standards ensure quality delivered in an alternate site setting.

Providing infusion therapies at home has several advantages over hospital-based therapy. Most patients prefer to receive such therapies at home rather than in the hospital or in a skilled nursing facility. Homecare therapy allows many patients to lead normal lives throughout the duration of the therapy; it enables terminally ill patients to spend valuable time with their families and loved ones. Also, the ability to administer these therapies in the home reduces the risk of hospital-acquired infections that are sometimes associated with prolonged in-patient stays. In most cases, the cost of infusion drug therapy when properly provided in the home is far less than the cost of such care in the hospital.

MEDICARE COVERAGE OF HOME RESPIRATORY AND INFUSION INHALATION THERAPIES

It is important to note that Medicare covers very few of the infusion drug therapies when provided at home. Further, as I stated above, Medicare does not have a separate inhalation therapy benefit or a home infusion therapy benefit. Medicare coverage for these therapies in the home is found only under the DME benefit—but only when equipment such as a nebulizer or an infusion pump is necessary. The fact that coverage for these therapies is limited to the DME benefit is a very important point in understanding the homecare community's issues with drug reimbursement, because the DME benefit explicitly covers only the drugs, supplies, and equipment. There is no recognition of the professional services and other functions that are widely recognized as necessary to providing inhalation and infusion drug therapies in the home in a safe and effective manner.

The Medicare program's lack of recognition of these professional services is illogical, potentially threatening to beneficiaries, and contrary both to how clinicians define and the private sector plans cover these therapies. The clinical value and necessity of the provision of professional services to deliver inhalation and infusion therapies is reflected in various accreditation standards commonly used by private sector payers, such as the standards established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Indeed, private payers pay for these services as a specific component of the benefit. The Lewin Group's analysis provides a good picture of the costs involved in providing such services.

These therapies require specialized pharmacy services. Such services include the compounding of many of the drugs in a sterile setting, responding to emergencies and questions regarding therapy, and participating in the training and education of the patient (and often the patient's family). These therapies also require the services of a nurse or respiratory therapist to perform a variety of functions, including patient screening and assessment, patient training regarding administration of the pharmaceuticals, and general monitoring of the patient's health status. In the case of infusion therapy, these services also include care for the infusion site, and monitoring of the catheter exit site for signs of infection or other complications. In addition, the drug, supplies, and equipment are delivered to the patient's home often within four hours of the prescription. Patient satisfaction and other outcomes are measured and reported to accrediting organizations as part of quality improvement programs. Finally, staff, including licensed pharmacists, pharmacy technicians, respiratory therapists, and registered nurses, are on call 24 hours a day.

It is important to underscore that none of the specialized pharmacy services is covered under any other Medicare benefit. In a minority of cases, Medicare home infusion patients may meet the "homebound" requirement and qualify for the home health benefit. In such instances, the nursing services described above would be covered under that benefit. For all other Medicare Infusion Patients, the nursing services are not covered by the home health benefit.

AVERAGE WHOLESALE PRICE AND DRUG PRICING ISSUES

Much has been said about how Medicare pays for the few outpatient drugs that are covered currently. The use of the average wholesale price (AWP) as the principal basis for determining reimbursement for drugs has received much criticism recently

as being an inaccurate reflector of the physicians' and pharmacists' costs for these drugs. There is little question that these criticisms are correct—if the payment "buys" drugs only. In actual fact, the drug payment calculated on the basis of AWP has been used for far more than that. With regard to inhalation and infusion therapy in the home setting, the drug payment is the only available payment mechanism for needed functions that are essential to providing good quality care. In other words, the spread between the providers and suppliers' acquisition cost and the Medicare reimbursement under Medicare Part B must cover all functions and services. The acquisition cost of the drug is only a fraction of the overall cost of caring for these patients at home.

The conclusions of the Lewin report, which Dr. Lamphere will explain in more detail, reinforce the point that the cost of the drugs represents only one small portion of the overall cost of caring for these patients in need of inhalation or infusion therapy. Indeed, the cost of goods represents 26% of total costs while direct patient care costs average 46% and indirect costs such as accreditation, information systems, and Medicare/Medicaid regulatory compliance amount to another 25%.

In the case of infusion therapies delivered to Medicare beneficiaries, providers, and suppliers, costs exceed the revenues received under Medicare. For respiratory medications, providers and suppliers report an average margin of 9.2% after taxes, which is considerably less than the average after tax margin of 14.4% reported by companies on the S&P index for the same time period in 2000.

It is important to note that homecare providers are not engaged in the selection of a particular drug. Physicians prescribe exactly which drugs should be used. The services furnished by homecare providers and suppliers are triggered by the physician's prescription. Their jobs begin when they receive the physician's order.

Policymakers simply cannot look at drug payment as an isolated issue, separate from the other workings of a particular therapy. Reducing drug payments dramatically, without corresponding changes in other aspects of the payment methodologies, would truly strain the ability of suppliers and providers to continue to provide these drug therapies to Medicare beneficiaries. Indeed, homecare providers and suppliers are in a far more tenuous position regarding drug reimbursement than are other providers because they receive *no payment whatsoever* for the important functions and services. Reimbursement for drug therapies delivered in the home is tied solely to the drug supplies and equipment. There is no fee schedule for services. These necessary professional services must be recognized, and they should be reimbursed.

While we have analyzed the AWP system and possible alternatives, we have not been able to develop a recommendation for the Subcommittees for a system that accurately determines the cost of products to providers and suppliers. These costs vary so widely among providers and suppliers that it is difficult to conceive of a system that accurately accounts for all of these variables. Accordingly, we urge Congress to proceed with caution. However, if Congress contemplates changing the reimbursement system under Part B for drugs administered in the home, it is critical that it recognizes the services involved and provide a framework for reimbursing them. It is not an option, in our opinion, to limit payment and coverage strictly to what is covered under the DME benefit. If Medicare beneficiaries receive only what the DME benefit currently recognizes—the drug, supplies, and equipment (pump or nebulizer)—then the level of care for the Medicare beneficiaries will be far less than that commonly provided in the private sector. Indeed, there are questions whether there will be access for Medicare beneficiaries at all. That result would be neither fair nor clinically appropriate. Medicare beneficiaries often are less able to deal with the complexities of these technical homecare therapies than are people who are decades younger.

RECOMMENDATIONS

We believe that it is important to establish accurate definitions of home respiratory and infusion therapy, create quality standards based on those currently and widely used in the private sector, and establish a fee schedule that reflects all the covered components of the therapies. H.R. 2750, introduced earlier this year by Congressman Engel of New York, Congressman Rush of Illinois, Congressman Towns of New York, and Congresswoman Hart of Pennsylvania, would do exactly that for Medicare coverage of home infusion therapy. This bill would remove coverage of home infusion therapy from the DME benefit and establish a new benefit that accurately reflects how these therapies are and should be provided. If enacted, this bill will bring the Medicare program in-line with the private sector as to how these therapies are covered and defined. We believe this approach is equally appropriate for inhalation therapies provided in the home if Congress revises the reimbursement system for Medicare Part B and drugs.

Mr. Chairman, AAHomecare thanks you for the opportunity to present views on behalf of our member companies. Please do not hesitate to call upon us for additional information.

TESTIMONY OF JoANN LAMPHERE

Ms. LAMPHERE. Mr. Chairman, my name is JoAnn Lamphere. Thank you for the opportunity to present key findings of the Lewin Group's study. The significance of this study is that it supplies the most current and extensive estimates of the cost of respiratory and infusion therapies and the cost of the services that accompany quality patient care to Medicare beneficiaries in the home.

This past summer the Lewin Group surveyed 19 home pharmacy companies that served Medicare patients in all 50 States. A description of the study's analytic approach is in our report. Key findings of the study include pharmacy, nursing coordination, patient education, and other direct costs account for 46 percent of the total costs incurred by pharmacies providing respiratory and infusion therapies to Medicare patients. Medicare does not currently recognize these costs. The acquisition cost of the drug itself accounts for 26 percent. Indirect costs and bad debt account for another 28 percent. The distribution of direct patient costs varies by type of therapy. For respiratory therapy service costs equal 46 percent. For home infusion service costs range from 40 percent for chemotherapy to 26 percent for antiinfectives. Pretax operating margins are 20.5 percent for respiratory and negative 22.2 percent for home infusion services. The bottom line after-tax Medicare margin is 9.1 percent, which represents the combined margin for respiratory and infusion therapies provided to Medicare patients by home care providers after corporate income tax and interest and depreciation are recognized.

If we are to assure that Medicare beneficiaries across the United States have access to medically prescribed respiratory and infusion therapies in the home, these companies must continue to be financially viable.

Mr. Chairman, thank you.

[The prepared statement of JoAnn Lamphere follows:]

PREPARED STATEMENT OF JOANN LAMPHERE, THE LEWIN GROUP

Mr. Chairman. My name is JoAnn Lamphere, Dr.P.H. I am a Senior Manager in the Health Care Finance Practice of The Lewin Group. Thank you for the opportunity to present key findings of a study that The Lewin Group conducted for the American Association for Homecare. The purpose of this study was to determine the costs to providers associated with the clinical and support services offered to Medicare patients receiving respiratory and home infusion therapies in the home.

The significance of this study is that it provides the most current and extensive estimates of the cost of respiratory and infusion medications and the cost of the associated services that accompany quality patient care. This information should be useful to you in the months ahead as you consider the adequacy of Part B payments for drugs and biologicals under the Medicare program.

This past summer, The Lewin Group surveyed 19 home pharmacy providers. The sample was selected with the intent of representing homecare pharmacy companies nationwide. As a group, the sampled providers serve Medicare patients nationwide in all 50 states. The sampled companies range in size from less than $1 million to greater than $1 billion in annual net revenue. Sampled companies served 164,782 respiratory and 2,400 home infusion Medicare patients in CY 2000.

A chief financial officer (or designee) or head pharmacist from each participating company completed a mail-in survey; the information they provided was based on company financial records. The Lewin Group validated data submitted through fol-

low-up telephone interviews and available secondary data sources. The information that respondents provided included Medicare revenues, acquisition cost of goods, cost of pharmacy operations and other direct patient care, and other major costs that accompany the provision of respiratory and home infusion therapies to Medicare patients in the home. (Respondents were directed to exclude any costs and revenues associated with skilled nursing services that are reimbursed through home health agency provisions of Medicare.) Respondents were asked to proportionally allocate specified Medicare service expenses based on the volume of Medicare patients they served.

In a study such as this, it is important to assure that findings are not biased by a small sample size. To achieve this objective, a double weighting process was adopted. First the sample of homecare pharmacies was divided into two groups, large companies and small companies, based on volume of their respiratory and home infusion business. Revenues and costs were then pooled at the "large" and "small" company levels and sampled companies' respiratory and home infusion service costs and margins were calculated from these numbers. Next, an additional set of weights was employed in order to ensure that calculations from the sample reflect the industry's distribution of large and small firms with respect to Medicare respiratory and home infusion services. Thus, the Lewin estimates of Medicare product and service costs for respiratory and home infusion therapies and Medicare operating margins were calculated in such a way that they are broadly representative of the homecare pharmacy industry as a whole.

What was learned from this Lewin study? Our key findings include:

- Pharmacy operations, patient care and education, and other direct costs account for 46 percent of the total cost incurred by homecare pharmacies providing respiratory and home infusion therapies to Medicare patients. The acquisition cost of the goods themselves account for about 26 percent of the total cost, on average.
- The distribution of costs for pharmacy operations, direct patient care, and other services varies dramatically by type of therapy. For respiratory therapy, service costs equal 46 percent of the total cost of providing respiratory services in the home. For home infusion therapies, service costs range from a high of 40.2 percent for chemotherapy and 38.7 percent for pain therapy and management to 25.8 percent for anti-infectives and 26.4 for inotropic therapy.
- Indirect costs, such as management systems, regulatory compliance programs, field administration, and bad debt make up the remaining 28 percent of home pharmacy costs.
- We analyzed pre-tax operating margins individually for respiratory and infusion therapies. Pre-tax operating margins are 20.5 percent for respiratory and -22.2 percent for home infusion services. Combined, pre-tax operating margin for both services is 20.4 percent.
- The bottom line after-tax margin for sampled companies is 9.1 percent. This 9.1 percent is the estimated combined margin for respiratory and home infusion services provided to Medicare patients by home pharmacy companies after federal and state corporate income taxes, as well as interest and depreciation, are recognized.

Assuring quality patient care and meeting established patient quality care standards (e.g., accreditation, federal and state licensure and regulatory requirements, etc.) is an essential component of the service homecare pharmacy providers offer to all patients, regardless of whether Medicare reimbursement policies expressly recognize these services.

Currently, Medicare Part B reimbursement for drug products offsets the costs of important patient services for which there is no direct Medicare payment. The financial realities of the health care marketplace that provides respiratory and infusion therapies to Medicare patients at home require a positive after-tax margin in order to attract equity capital for future operations. Thus, if we are to assure that Medicare beneficiaries across the United States have access to medically prescribed respiratory and home infusion therapies in the home, these companies must continue to be financially viable.

Mr. Chairman. Thank you for the opportunity to present these findings from The Lewin Group's study. A copy of the full report, on which this testimony is based, is provided for your consideration.

Mr. GREENWOOD. Thank you very much for your testimony. Dr. Emanuel for 5 minutes.

TESTIMONY OF EZEKIEL EMANUEL

Mr. EMANUEL. Thank you, Mr. Chairman and members of the subcommittee, for inviting me to testify. I am Ezekiel Emanuel, an oncologist and bioethicist, and I work at the NIH as the Chair of the Department of Bioethics. I also am Chairman of the American Society of Clinical Oncology's Task Force on Quality of Cancer Care.

Let me start by saying what I am not. All my life I have worked in an academic setting at Dana-Farber Cancer Institute at the NIH, and I have never once billed Medicare for any chemotherapy I administer, so I know very little about AWP.

The primary purpose of my testimony, however, is to talk to you about a study we conducted to look at the use of chemotherapy at the end of life. This is an area I've been interested in for about 15 years. As you know, there's widespread perception among the public that dying cancer patients receive too much chemotherapy. Conversely, my colleagues believe that dying patients and their families often demand chemotherapy and that they use chemotherapy judicially at the end of life to enhance quality of life and prolong life. Ironically, there is no data on this subject and it's never been looked at before. We looked at nearly 8,000 patients in Massachusetts who died of cancer. Let me just summarize six of our findings.

First, in the last 6 months of life about 33 percent of patients who died of cancer received chemotherapy and almost a quarter of patients received chemotherapy in the last 3 months of their life.

When we compared—second point, when we compared patients who had chemotherapy responsive tumors like breast cancer, colon cancer, ovarian cancer, with patients who had at that time chemotherapy unresponsive tumors, tumors that did not shrink with chemotherapy like pancreatic cancer or liver cancer or gall bladder cancer, we found no difference in the frequency with which the chemotherapy was given. So it was given as frequently to chemotherapy responsive tumors as chemotherapy unresponsive tumors.

Third, dying patients who were younger were much more likely to get chemotherapy than older patients regardless of cancer type.

Fourth, how long dying patients receive chemotherapy, however, differed very much by the type of cancer patients had, so that those patients who had chemotherapy unresponsive tumors like pancreatic cancer or liver cancer got chemotherapy for only one cycle whereas those people who had breast cancer and colon cancer tended to get more chemotherapy.

Fifth, unlike lots of other previous studies we found that patients who received chemotherapy at the end of life had substantially higher Medicare costs than patients who did not receive chemotherapy, up to a third more.

Finally, let me make the point that these data are not unique to Massachusetts. We did a small sample just to verify looking at California patients and found very similar data, although the exact numbers varied.

How might these data affect the hearing here? One of the important questions is why are people getting chemotherapy at the end of life? What motivates people? There are several potential explanations. Let me highlight several.

First, I have to admit I can't tell you from these data exactly why each patient got chemotherapy. We just looked at the Medicare data and it's very hard to draw motivations. But one potential explanation is that many cancer patients, as mentioned by Congressman Ganske, need or want chemotherapy at the end of life, especially when they get diagnosed with a terminal illness, they go to an oncologist, they have no previous relationship and they want to try anything. Oncologists acquiesce, give the chemotherapy, and patients then find out they may not like it and that is why you get a lot of patients getting only one cycle of chemotherapy.

Another potential explanation is that chemotherapy does, we know, improve quality of life of patients. It's very hard for those of us who are healthy, who have never had cancer, who recognize the side effects, the nausea, the vomiting, baldness, that this might improve quality of life, but there are a number of studies showing that with lung cancer, colon cancer, ovarian cancer, chemotherapy improves pain and improves quality of life of dying patients.

A third potential explanation is that we're just uncertain about this, how long in fact are they going to live, and we are always cautious, so we would use chemotherapy.

A fourth potential explanation is that oncologists may give chemotherapy for a financial reimbursement, the spread between AWP and what they get.

I want to emphasize from my data I can't tell you which of these explanations is right, and we need a lot more research to tell how much these factors influence people. But one of the major concerns by our study I think is revealed when you contrast it with other data we have from Medicare, and I want to highlight data from colleagues of mine at Memorial Sloan-Kettering. They recently looked at chemotherapy administered to patients with colon cancer where we know the chemotherapy prolongs life and can cure patients, and they revealed that only 55 percent of Medicare patients with colon cancer actually got chemotherapy. This is chemotherapy for which doctors would be reimbursed the same amount as in other cases, and so we know there are cases where there is overuse and cases where there is under use.

And this leads me to this issue: While we are focusing on costs here, let me suggest that there is a bigger issue, and that is that we as oncologists cannot guarantee Americans who are diagnosed with cancer get optimal cancer care. Sometimes they may get too much chemotherapy, sometimes too little, even when oncologists are being reimbursed to give them chemotherapy. And I think that what we really need to figure out is how we're paying for quality cancer care and that people who need the drugs get the drugs, and that's actually why I have been working with ASCO on a $5 million project to try to figure out how we can get quality cancer care and what are the barriers to getting people the right drugs at the right time that prolongs their life and improves their quality of life.

Thank you very much for inviting me, and I will be happy to answer any of your questions.

[The prepared statement of Ezekiel Emanuel follows:]

PREPARED STATEMENT OF EZEKIEL EMANUEL, CHIEF, CLINICAL BIOETHICS DEPARTMENT, WARREN G. MAGNUSON CLINICAL CENTER, NATIONAL INSTITUTES OF HEALTH

There is substantial concern about end-of-life care provided to Americans. In particular, a number of commentators are concerned that dying cancer patients are frequently overtreated with chemotherapy. Critics contend that many oncologists overtreat dying patients with chemotherapy because they are reluctant to accept death and apprehensive about discussing end-of-life care.[1,2,3] Indeed, some critics contend that oncologists prey on their patients' vulnerability, implying that chemotherapy is the vehicle of hope, and pressing them to try it before reconciling themselves to death.[4] Oncologists respond that it is terminally ill patients who demand treatment. More importantly, oncologists contend that they use chemotherapy prudently in patients at the end of life, when it is likely to provide symptom relief and enhance dying patients' quality-of-life.

How can we determine if chemotherapy is used too frequently for terminally ill cancer patients? There are no standards for the appropriate use of chemotherapy at the end of life based upon either randomized controlled trials or expert, consensus guidelines. While there are some data on treatment of patients with metastatic cancers,[5] even basic data on how frequently cancer patients are given chemotherapy in the months before death are lacking. To explore whether chemotherapy is used prudently and rationally at the end of life, we separately examined its use among Massachusetts and California Medicare beneficiaries who died of cancer in 1996. Dividing patients into two groups according to whether they died of cancers responsive or unresponsive to chemotherapy, we evaluated the use of chemotherapy, and the expenditures in the last year of life.

METHODS

Identifying Cancer Decedents: To focus only on persons who died from cancer—not merely with cancer—based on the primary cause of death listed in the death certificate, we followed a 3-step process. First, in both Massachusetts and California we studied fully entitled Medicare beneficiaries who died in 1996, were at least 66 years old at death and were not enrolled in Medicare's End Stage Renal Disease program. Decedents 66 years of age were selected to ensure we obtained a full year of Medicare expenditure data prior to death. We studied all such decedents in Massachusetts and 5% in California. Second, we merged HCFA's denominator files with each state's 1996 death certificate files. In Massachusetts, 42,452 Medicare decedents met the criteria. In merging the files we used social security number (SSN), date of birth (DOB), date of death (DOD) and sex. A match was accepted if either of the following conditions was met: 1) there was a perfect match on SSN and either sex or both DOB and DOD or 2) a match on at least 7 of SSN digits and a perfect match on sex, DOB, and DOD. Of the 42,452 decedents, there was a match between the HCFA files and death certificates for 39,447 (92.9%). Only beneficiaries continuously enrolled in both Parts A and B Medicare insurance and who were not enrolled in an managed care organization over the entire last 12 months of life were retained, yielding 34,131 Massachusetts decedents. Third, we selected the 7,919 decedents whose primary cause of death listed on the death certificate was cancer.

In California, the same general protocol was applied to a random 5% of Medicare enrollees yielding 4,715 total decedents overall, of which 956 died of cancer.

Classifying Cancer Types: We classified breast, colon, and ovarian cancers as chemotherapy responsive solid cancers. Multiple chemotherapeutic agents shrink these cancers, and randomized trials have shown chemotherapy to be effective in prolonging lives of patients at least as adjuvant therapy. We classified pancreatic, renal cell, hepatocellular, gallbladder, cancers, and melanoma as chemotherapy unresponsive solid cancers. In 1996, these cancers were known to be "refractory to virtually all chemotherapeutic agents" such that the general consensus in standard textbooks is that "there are no particularly compelling cytotoxic chemotherapeutic agents [with which] to treat" them.[6]

We examined data for other cancers that we did not categorize as responsive or unresponsive. For example, while prostate cancer is generally considered a chemotherapy unresponsive solid cancer, hormonal injections may appear in claims data as chemotherapy. To avoid uncertainty, prostate cancer is reported separately. Lung cancer also examined separately because using claims data, it is impossible to differentiate lung cancers into small cell and non-small cell (NSCLC) tumors. Furthermore, while small cell cancers are chemotherapy responsive, using chemotherapy for metastatic non-small cell lung cancers is highly controversial.[7] Data suggest that chemotherapy for NSCLC extends life by 6 weeks and may improve quality-of-life despite toxicities.[8,9,10] Finally, hematological malignancies, encompassing both acute

and chronic leukemias, Hodgkin's disease, and all non-Hodgkin's lymphomas, were analyzed separately. Although they are chemotherapy responsive, patients may die acutely from treatment related toxicities.

Identifying the Use of Chemotherapy: Patients who had claims in the inpatient, outpatient or physician/supplier Medicare files for chemotherapy agents, chemotherapy administration, or the medical supervision of chemotherapy were considered to as having received chemotherapy. The codes used were: intravenous chemotherapy agents—HCPCS codes 964XX, 965XX, J9000-9999; chemotherapy administration—IC Procedure 99.25, HCPCS codes Q0083-Q0085; medical evaluation for chemotherapy—ICD Diagnosis V58.1, V66.2, and V67.2. It is possible that our method of identifying chemotherapy missed patients who received oral chemotherapeutic agents. Patients without claims using these codes were classified as not having chemotherapy.

We examined chemotherapy use for decedents for 30-day periods from the date of death back for 12 months.

Expenditure Data: Total expenditure is calculated as the sum of HCFA payments and payments from other sources of insurance for Medicare covered services. The average payment per person from other insurance accounts for only 0.15% of costs. Expenditures for each decedent are calculated from 5 HCFA files: 1) Medicare Provider Analysis and Review (MedPAR), including acute hospitalizations, long term hospitalizations, and skilled nursing home care; 2) Hospital outpatient; 3) Part B physician-supplier; 4) Home health care; and 5) Hospice. Durable medical equipment (DME) expenses were excluded, but in Massachusetts, they contributed just $400 per person over the last year of life.

RESULTS

Frequency of Chemotherapy in the Last Months of Life: Figure 1 shows that 41% of our study population in Massachusetts received chemotherapy in the last year of life. Fully 33% of Massachusetts cancer decedents received chemotherapy in the last 6 months of life, 23% in the last 3 months of life, and 9% of cancer decedents received chemotherapy in the very last month of life.

Table 1 provides data on the proportion of terminally ill cancer patients treated in Massachusetts with chemotherapy in the last 6, 3 and 1 months of life. Patients who died of hematological malignancies received chemotherapy most frequently, with more than half getting chemotherapy in the last 6 months of life and 19% in the last month of life. Massachusetts patients with chemotherapy unresponsive solid cancers received chemotherapy at about the same frequency as patients with chemotherapy responsive solid cancers (Table 1). Among patients with chemotherapy unresponsive solid cancers taken together (pancreatic, hepatocellular, gallbladder, and renal cell cancers and melanoma) 23% received chemotherapy in the last 3 months of life, which was the same as the percentage of patients with chemotherapy responsive cancers (breast, colon, ovarian) that received chemotherapy.

An interesting example of the use of chemotherapy at the end of life is pancreatic cancer. In the last 6 months of life, 33% of Massachusetts patients dying of pancreatic cancer received chemotherapy, 25% in the last 3 months, and 8% in the last month of life. On May 15, 1996, the FDA approved gemcitabine as the first agent shown to be effective in pancreatic cancer. Prior to this date, when there were no effective agents, 28% of patients dying of pancreatic cancer received chemotherapy in the last 6 months of life. After May 15th, 37% received chemotherapy (one-sided $p=0.04$).

A comparison of the chemotherapy unresponsive melanoma and renal cell cancer with chemotherapy responsive breast and colon cancers is also instructive. Of patients dying of melanoma, 21% received chemotherapy in the last 3 months of life and 10% in the last month of life. Similarly, among patients dying of renal cell cancer, 22% received chemotherapy in the last 3 months of life and 7% in the last month of life. Surprisingly the frequency of chemotherapy for dying breast and colon cancer patients was almost identical. 22% of patients dying of breast cancer received chemotherapy in the last 3 months and 8% in the last month of life. Similarly, 23% of patients dying of colon cancer received chemotherapy in the last 3 months and 7% in the last month of life.

There are no substantial differences in the use of chemotherapy by sex (Table 1). However, the use of chemotherapy at the end of life is age related. Among Massachusetts patients 65-74 32% received chemotherapy in the last 3 months of life, compared to 22% for patients 75 to 84 year old, and 11% for patients over 85 years of age (Table 1). These variations by age were similar in chemotherapy unresponsive and responsive solid cancers (Table 2). Overall, 13% of 85 year olds with chemotherapy unresponsive solid cancers received chemotherapy in the last 3 months of

life compared to 10% of 85 year olds with chemotherapy responsive solid cancers (Table 2).

Number of Months of Chemotherapy in the Last Months of Life: Among Massachusetts patients who received chemotherapy in the last 6 months of life, 41% had a short "trial," just one month or less of chemotherapy, with 36% receiving chemotherapy for 1 to 3 months, 23% 4 or more months of chemotherapy (Table 3). The number of months of chemotherapy did not depend on sex, but did depend upon age (Table 3).

Importantly, the chemotherapy responsiveness of the solid cancers was associated with a difference in the number of months of chemotherapy provided to decedents (Table 3). Among Massachusetts patients dying of chemotherapy unresponsive tumors who received chemotherapy, over half received 1 month or less of chemotherapy and 31% received chemotherapy for 1 to 3 months. Conversely, among patients dying of chemotherapy responsive cancers who received chemotherapy a third received 1 month or less of chemotherapy and 40% received chemotherapy for 1 to 3 months of the last 6 months of life. Notably, 17% of patients dying from chemotherapy unresponsive cancers had 4 or more months of chemotherapy (Table 3).

Returning to patients with pancreatic cancer, 49% received chemotherapy for 1 month or less, 34% for 1 to 3 months and 3% during each of the last 6 months. For patients dying of breast cancer, 32% received chemotherapy for 1 month or less, 39% for 1 to 3 months and 5% across all 6 final months.

The Use of Chemotherapy and Expenditures: Annual expenditures for dying Massachusetts cancer patients who received chemotherapy in the last 6 months of life were 32.5% higher than patients who did not receive chemotherapy ($39,707 v. $29,974) (Table 4). Annual expenditure for patients with chemotherapy unresponsive cancers who received chemotherapy was $33,365 about 10% less than the expenditure for patients with chemotherapy responsive cancers who received chemotherapy ($36,684). Expenditures for patients with chemotherapy unresponsive cancers who received chemotherapy were 20% more than for patients with the same cancers who did not receive chemotherapy ($33,365 v. $27,737), while expenditures for patients with chemotherapy responsive cancers who received chemotherapy were 23.9% more than for patients with the same cancers who did not receive chemotherapy ($36,684 v. $29,610).

Comparison with Cancer Decedents from California: We used decedents our sample of 956 cancer decedents from California to test whether our findings in Massachusetts might apply more generally (Table 5). Among California cancer decedents, 26% received chemotherapy in the last 6 months of life, 20% in the last 3 months and 9% in the last month of life. Among decedents with chemotherapy responsive tumors, 17% received chemotherapy in the last 3 months of life compared to 20% for the chemotherapy unresponsive tumors.

Similarly, use of chemotherapy at the end of life was age related in California for both chemotherapy responsive and unresponsive cancers. Among decedents aged 65-74, 26% of those with chemotherapy responsive tumors compared to 32% of those with chemotherapy unresponsive tumors received chemotherapy in the last 3 months of life. Similarly, among decedents aged 75-84 19% of those with responsive tumors compared to 18% of decedents with unresponsive tumors received chemotherapy in the last 3 months of life. Overall, 25% of patients with chemotherapy responsive tumors receiving chemotherapy received less than 1 month of chemotherapy while 35% of those with chemotherapy unresponsive tumors did so.

DISCUSSION

This study provides insight into the frequency of use of chemotherapy at the end of life. Overall 33% of Medicare patients dying of cancer in Massachusetts in 1996 received chemotherapy in the last 6 months of life and nearly a quarter in the last 3 months. Most surprisingly, patients dying of chemotherapy unresponsive cancers, such as pancreatic, gallbladder, renal cell, and hepatocellular cancers, were just as likely to receive chemotherapy at the end of life as patients dying of chemotherapy responsive cancers, such as breast, colon, and ovarian cancers. This suggests overuse of chemotherapy at the end of life, at least among patients with chemotherapy unresponsive cancers.

Traditionally, to document over- and underuse of health care services, studies compare claims data with optimal practices established by randomized controlled trials or by expert, consensus panels. Lacking randomized trials or consensus panels to establish standards for the appropriate use of chemotherapy at the end of life, we examined tumor responsiveness to chemotherapy. Cancers are traditionally divided in those that are chemotherapy responsive, in which chemotherapy can commonly induce complete and partial responses, compared to those in which chemo-

therapy rarely leads to tumor shrinkage. In our data, lack of responsiveness of the cancer to chemotherapy did not reduce the prevalence of chemotherapy use. Patients with unresponsive cancers were just as likely to receive chemotherapy in the last few months of life as patients with chemotherapy responsive cancers. Indeed, patients with unresponsive cancers were slightly more likely to receive chemotherapy than patients with lung cancer in which data suggests chemotherapy in the last 6 months of life, may extend life by a few weeks and even palliate symptoms.

Although patients dying of chemotherapy unresponsive solid cancers received chemotherapy as frequently as those with responsive cancers, they received fewer months of chemotherapy. This suggests some selectivity in the use of chemotherapy at the end of life. It is possible that after one cycle of therapy many patients and oncologists are convinced by ineffectiveness and/or the side effects to stop treatment for chemotherapy unresponsive cancers. Nevertheless, 17% of patients receiving chemotherapy for chemotherapy unresponsive cancers received chemotherapy during four or more of the final 6 months of life.

Many reasons may explain the use of chemotherapy at the end of life for patients with unresponsive cancers. The most reasonable explanation may be that patients and families demand to at least "try" to see if chemotherapy might shrink the cancer. Oncologists frequently meet patients for the first time right after they have been newly diagnosed with chemotherapy unresponsive tumors that present a bleak prognosis. These patients and their families often want to try anything that might shrink their cancers. Indeed, data suggest that cancer patients are willing to endure significant side effects for very small prolongations in life.[11,12] Lacking an established relationship with the patient or family and confronting an emotional demand to try anything, oncologists may acquiesce. One cycle of chemotherapy is often sufficient for patients and families to adjust and absorb the realities of the diagnosis, prognosis, and to realize the ineffectiveness of the chemotherapy and the undesirable side effects. That over half of the patients receiving chemotherapy for unresponsive cancers received 1 month or less of chemotherapy strongly supports this explanation. Obviously, additional research is necessary to provide insights into how much of a role patient and family demand plays in the use of chemotherapy at the end of life.

Other potential reasons for the use of chemotherapy at the end of life include uncertain prognosis and time of death, uncertain responsiveness of the cancer to chemotherapy, and use of experimental chemotherapies. These reasons are unlikely to account for our data on chemotherapy unresponsive solid cancers. While the exact date of death cannot be known in advance, cancers, especially chemotherapy unresponsive solid cancers, are unlike the terminal phases of COPD or heart failure; they tend to have a monotonic, unremitting decline to death despite all interventions.[13] Typically within the last three months of life, oncologists can predict, with reasonable certainty that the patient will die in a few months regardless of treatment. Furthermore, there is no real uncertainty about the chemotherapy unresponsiveness of the solid tumors we classified as "unresponsive." Finally, although some patients may be receiving experimental chemotherapy, this is likely to be rare among Medicare beneficiaries who are often ineligible due to age and comorbidities.

Yet another potential explanation for the use of chemotherapy for patients with unresponsive cancers is that chemotherapy may improve quality of life and palliate symptoms for dying patients even if it fails to prolong life or shrink tumors.[14,15] There are some data supporting the palliative effect of chemotherapy for lung and colon cancer and some suggestions that this might also operate in ovarian cancer.[16,17,18,19] Frequently, emotional functioning and fatigue are the quality-of-life subscales with the most improvement. That these improvements occur without objective tumor responses suggests that they may be related to patient expectations or possibly the placebo effect of chemotherapy, rather than any biological impact.[20] The mechanism by which chemotherapy in terminal phases may palliate without objectively shrinking cancers requires further research.

The similar frequency of chemotherapy use regardless of the responsiveness of the cancer may be because near terminal patients with breast, colon, and ovarian cancers may have been treated with many different chemotherapy regimens and their cancers may have become chemotherapy resistant. In this way, patients dying of chemotherapy responsive tumors may be more like decedents with chemotherapy unresponsive cancers. This does not justify using chemotherapy for unresponsive tumors. It also raises the question of whether providing chemotherapy in the last 3 months of life to nearly a quarter of cancer patients whose tumors have become resistant to chemotherapy is itself an indication of overuse.

This study suggests that use of ineffective chemotherapy consumes substantial medical resources. Annual expenditures for patients who received chemotherapy, regardless of the responsiveness of the cancer, were 32.5% higher than for patients

who did not receive chemotherapy in the last 6 months of life. Among patients who died of chemotherapy unresponsive cancers, the use of chemotherapy in the last 6 months of life was associated with 20% higher annual expenditures, or more than $5,500 per decedent. The extra amount spent on providing chemotherapy to patients dying of unresponsive cancers is comparable to the average annual expenditure for all Medicare beneficiaries and nearly one third higher than annual per capita health expenditures in the U.S. These data contrast with studies suggesting that compared to "best supportive care" chemotherapy for non-small cell lung cancer does not increase, and may even decrease medical costs.[21,22,23] The disjunction between our results and these studies may arise because of the difficulty in translating results of randomized trials into actual clinical practice. Care protocols in research may limit use of unnecessary interventions, whereas in actual clinical practice use of treatments, hospitalizations, and other interventions vary more. Furthermore, the cost data on best supportive care come only from Canada and are more than a decade old21-23, and patients receiving best supportive care were frequently hospitalized, using more hospital days than patients receiving chemotherapy. These old data, especially of hospitalizing patients receiving "best supportive care" reflect practices not found in these data and unlikely to still be common. It may also be that in actual clinical practice patients not receiving chemotherapy may not be receiving "best supportive care" reducing expenditures.

Finally, this overuse of treatment at the end of life is particularly wasteful when placed in the context of the documented underuse of treatments proven by randomized controlled trials to be effective in prolonging life. Studies have shown that only 55% of Medicare beneficiaries receive adjuvant chemotherapy for Stage III colon cancer.[24] Indeed, among 85 year old patients the use of chemotherapy for Stage III colon cancer is 11% less than the frequency of the use of chemotherapy in the last 3 months for 85 year olds with chemotherapy unresponsive cancers. Unfortunately, it appears that there may be overuse of chemotherapies in the last few months of life coincident with underuse of therapies known to be effective in prolonging life.

In health care, Massachusetts is known as a high use and high cost state.[25] A major issue is whether these data on chemotherapy use at the end-of-life are unique to Massachusetts or are generalizable. While there are some differences in the absolute use of chemotherapy for some cancers, our data from California, although limited, suggest a similar pattern of use of chemotherapy at the end of life. In California one in five cancer decedents receive chemotherapy in the last 3 months of life, and this does not differ between chemotherapy responsive and unresponsive cancers. Clearly, these results need to be confirmed in other, larger populations. However, these data show that the situation in Massachusetts is not unique.

This study has some significant limitations. First, the data may not generalize in other ways. Chemotherapy use among decedents under 65 years of age might be different. The strong trends toward greater use of chemotherapy among younger decedents suggests these data might actually underestimate chemotherapy use in the last 6 months of life among cancer decedents of all ages. Chemotherapy use in managed care settings also might differ. Second, we have no data on stage of cancer; some patients may have died from acute toxicities of chemotherapy without being terminally ill. However, data from trials suggest that acute toxic deaths among patients receiving adjuvant therapy are rare, and thus unlikely to account for a substantial proportion of cancer mortality.[26] Indeed, adjuvant chemotherapies associated with high toxic mortality would be used infrequently. Third, the cause of death listed on death certificates is not always accurate. However, listing cancer as the cause of death may be insensitive, but it is specific, and Massachusetts and California are among the states with the most accurate death certificates. Fourth, annual expenditures were calculated but we tracked chemotherapy use only in the last 6 months of life. Decedents who received chemotherapy in the 7 to 12 months before death only are classified in the "no chemotherapy" group, increasing the costs of this group. This makes the difference in expenditures appear smaller than if the comparison had been with decedents who had received no chemotherapy in the entire last year of life. Most importantly, these data provide no explanation for why chemotherapy is provided in any particular case. Additional study is needed to determine the reasons why chemotherapy is used in the last 6 months of life, especially for chemotherapy unresponsive cancers.

CONCLUSION

There is substantial disagreement about whether chemotherapy is used appropriately in patients near the end of life. This study demonstrates that one third of patients in Massachusetts receive chemotherapy in the last 6 months of life, even

among those persons dying from chemotherapy unresponsive cancers. Oncologists should reconsider the use of chemotherapy at the end of life.

ACKNOWLEDGEMENTS

We would like to thank Joan Warren, Deborah Schrag, and Peter Bach for helpful advice and comments on the project and manuscript. We would also like to thank many questioners at the 2001 Annual American Society of Clinical Oncology meeting for helpful challenges.

Frequency of Patients Receiving Chemotherapy in the Last Months of Life

(This will be a figure)

	Massachusetts (N=7,919)
Last 1 month of life	9%
Last 2 months	17%
Last 3 months	23%
Last 4 months	28%
Last 5 months	31%
Last 6 months	33%
Last year of life	41%

TABLE 1: Characteristics of Massachusetts Cancer Decedents by Receipt of Chemotherapy in the Last 6 Months of Life

		All Cancer Decedents	Cancer Decedents Receiving Chemotherapy in Last:		
			6 months of life (N=2,625)	3 months of life (N=1,854)	1 month of life (N=715)
All Cancers		7,919	33%	23%	9%
Sex	Male	3,863	35%	22%	10%
	Female	4,056	31%	26%	8%
Age	65-74	2,926	44%	32%	12%
	75-84	3,392	31%	22%	8%
	85+	1,601	16%	11%	5%
Chemotherapy Responsive Solid Cancers	Total	1,627	34%	23%	%
	Breast	612	30%	22%	8%
	Colon	846	32%	23%	7%
	Ovarian	269	47%	30%	7%
Chemotherapy Unresponsive Solid Cancers	Total	870	31%	23%	9%
	Pancreas	408	33%	25%	8%
	Melanoma	84	30%	21%	10%
	Renal Cell	147	29%	22%	7%
	Hepatic and Gallbladder	231	29%	20%	8%
Other Types of Cancer	Lung	2,003	28%	19%	7%
	Prostate	602	39%	28%	10%
	Hematological*	760	51%	42%	19%
	All Other	2,057	30%	20%	9%

*Includes all acute and chronic leukemias, non-Hodgkin lymphomas, Hodgkin's disease, but excludes multiple myeloma.

TABLE 2: Massachusetts Cancer Decedents Receiving Chemotherapy in the Last 3 Months of Life by Cancer Type and Age

		Number of Patients Getting Chemotherapy in last 3 Months of Life	65-74 (N=2,926)	75-84 (N=3,392)	85+ (N=1,601)
All Cancers		1,854	32%	22%	11%
Chemotherapy Responsive Solid Cancers	Total	377	36%	21%	10%
	Breast	135	38%	19%	7%

TABLE 2: Massachusetts Cancer Decedents Receiving Chemotherapy in the Last 3 Months of Life by Cancer Type and Age—Continued

		Number of Patients Getting Chemo-therapy in last 3 Months of Life	65-74 (N=2,926)	75-84 (N=3,392)	85+ (N=1,601)
	Colon	191	33%	23%	11%
	Ovarian	51	43%	22%	17%
Chemotherapy Unresponsive Solid Cancers	Total	199	30%	22%	13%
	Pancreas	101	33%	24%	12%
	Melanoma	18	27%	19%	13%
	Renal Cell	33	36%	15%	10%
	Hepatic and Gallbladder	47	23%	21%	15%
Other Types of Cancer	Lung	371	28%	12%	6%
	Prostate	170	32%	34%	11%
	Hematological*	321	54%	44%	17%
	All Other	416	26%	20%	11%

*Includes all acute and chronic leukemias, non-Hodgkin lymphomas, Hodgkin's disease, but excludes multiple myeloma.

TABLE 3: The Number of Months of Chemotherapy Provided to Massachusetts Cancer Decedents Receiving Any Chemotherapy in the Last 6 Months of Life

		1 Month or Less>	1 to 3 Months>	3 Months	Mean Number of Months
All Cancers		41%	36%	19%	2.4
Sex	Male	38%	36%	20%	2.2
	Female	45%	36%	16%	2.5
Age	65-74	35%	39%	21%	2.5
	75-84	44%	35%	17%	2.3
	85+	59%	28%	11%	1.9
Chemotherapy Responsive Solid Cancers	Total	33%	40%	22%	2.6
	Breast	32%	39%	24%	2.6
	Colon	35%	41%	19%	2.5
	Ovarian	29%	39%	24%	2.8
Chemotherapy Unresponsive Solid Cancers	Total	52%	31%	14%	2.0
	Pancreas	49%	34%	14%	2.1
	Melanoma	56%	36%	0%	1.8
	Renal Cell	51%	37%	10%	2.0
	Hepatic and Gallbladder	59%	21%	17%	2.1
Other Types of Cancer	Lung	45%	39%	13%	2.2
	Prostate	30%	31%	31%	3.0
	Hematological*	32%	39%	22%	2.7
	All Other	50%	33%	14%	2.1

*Includes all acute and chronic leukemias, non-Hodgkin lymphomas, Hodgkin's disease, but excludes multiple myeloma.

TABLE 4: Expenditures in the Last Year of Life for Massachusetts Cancer Decedents by Receipt of Chemotherapy in the Last 6 Months of Life

		Decedents who Received No Chemo-therapy (N=)	Decedents who Received Chemotherapy (N=)	% Increase for Decedents Receiving Chemotherapy
All Cancers		$29,974	$39,707	32.5%
Sex	Male	$29,729	$39,539	33.0%
	Female	$30,193	$39,890	32.1%
Age	65-74	$32,551	$43,042	32.2%
	75-84	$31,155	$36,989	18.7%
	85+	$24,803	$34,055	37.2%
Chemotherapy Responsive Solid Cancers	Total	$29,610	$36,684	23.9%
	Breast	$26,817	$36,277	35.3%

TABLE 4: Expenditures in the Last Year of Life for Massachusetts Cancer Decedents by Receipt of Chemotherapy in the Last 6 Months of Life—Continued

		Decedents who Received No Chemo-therapy (N=)	Decedents who Received Chemotherapy (N=)	% Increase for Decedents Receiving Chemotherapy
	Colon	$31,435	$32,972	4.9%
	Ovarian	$30,870	$50,400	63.5%
Chemotherapy Unresponsive Solid Cancers	Total	$27,737	$33,365	20.3%
	Pancreas	$26,356	$35,371	34.2%
	Melanoma	$19,982	$32,717	63.7%
	Renal Cell	$32,923	$35,735	8.5%
	Hepatic and Gallbladder	$27,911	$29,275	4.9%
Other Types of Cancer	Lung	$29,750	$38,967	31.0%
	Prostate	$27,685	$34,167	23.4%
	Hematological*	$34,430	$52,619	52.8%
	All Other	$30,861	$39,830	29.1%

*Includes all acute and chronic leukemias, non-Hodgkin lymphomas, Hodgkin's disease, but excludes multiple myeloma.

TABLE 5: The Characteristics of California Cancer Decedents by Receipt of Chemotherapy in the Last 6 Months of Life

		All Cancer Decedents	Cancer Decedents Receiving Chemotherapy in Last:		
			6 months of life (N=253)	3 months of life (N=191)	1 month of life (N=85)
All Cancers		956	26%	20%	9%
Sex	Male	437	30%	24%	11%
	Female	519	23%	17%	7%
Age	65-74	323	39%	31%	12%
	75-84	444	25%	18%	9%
	85+	189	8%	6%	3%
Chemotherapy Responsive Solid Cancers		175	25%	17%	6%
Chemotherapy Unresponsive Solid Cancers		108	24%	20%	8%
Other Types of Cancer	Lung	280	23%	17%	8%
	Prostate	83	37%	27%	13%
	Hematological*	112	36%	29%	14%
	All Other	198	25%	19%	9%

*Includes all acute and chronic leukemias, non-Hodgkin lymphomas, Hodgkin's disease, but excludes multiple myeloma.

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Mr. GREENWOOD. Thank you, Dr. Emanuel, for your coming in and your helpful testimony. I appreciate that.

The Chair recognizes himself for 5 minutes to ask questions. Let me turn to Dr. Norton first.

It is evident from this hearing and from all of the work we've done leading up to this hearing, which has been extensive, that there is virtual unanimity among most Members of Congress with the GAO, the IG, the pharmaceutical industry, and your association that we need to get rid of AWP, that it's irrational, that it causes overpayments, cruel overpayments to beneficiaries. That is certainly inconsistent with what the intention of Medicare is. There is also, I would say, virtual unanimous consent to the notion that we need to then simultaneously, so that there is no disruption in service or no inequity imposed by our changes, come back with a way to make sure that your profession and all of the other professions that are here and that are not here who would be affected by a change in AWP are adequately and appropriately reimbursed.

Now, the GAO study says that in order to do that, we need to put about $51 million into increasing practice expenses. Mr. Scully from CMS testified that he thought the number was somewhere between $45 and $55 million and that those figures were arrived at totally independently, which gives us a fair amount of confidence in the order of magnitude of those changes.

Does your association—you have submitted a white paper, et cetera. I have a sneaking suspicion that your association thinks that the number might be a bit higher than that. Are you putting a number on the table here?

Mr. NORTON. We don't think we have the data—we don't think that anybody has the data to come up with an accurate number,

frankly. It gets down to fundamental logical issues about what it actually costs to give chemotherapy. The GAO report we haven't seen yet, the latest one. We thought that this issue is being studied carefully. We're—and I think we're going to have to scrutinize the report to see whether the report which just came out to today really does address the issue, but the only real way we feel that you can actually figure out the cost is to measure the cost of what is really required, how much nursing time is required, the cost of the syringe, the cost of the IV tubing, cost of the needles, the cost of the tape. All these things are costs, the inventory of drugs, spillage, wastage, all these issues that are involved, and we really don't have that data.

We will be very happy to do a survey to collect that data. We'll be very happy to work with the government, anybody who Congress designates to work to actually get that data, but just looking at this as a scientist, I don't think that the methods really are giving us the numbers we really need to figure out what the true costs are.

Mr. GREENWOOD. Thank you. While I am posing this next question, if Mr. Martyn and Mr. Connaughton would separate yourselves and, Mr. Scanlon, if you would bring a chair up and I am going to ask you to comment after I ask Dr. Norton another question.

In your testimony, Dr. Norton, you said that—and I am quoting—"Oncologists and their professional staffs typically furnish a variety of services to cancer patients for which there is no explicit reimbursement. These services include extensive support that seriously ill cancer patients frequently require, including social work services, psychosocial services, nutrition counseling. Social work services encompass a variety of services intended to help patients carry out their therapy, such as help with insurance, arranging transportation to treatment and filling prescriptions. Psychosocial support includes services such as counseling patients on their activities of daily living, support groups that meet in the physician's office and grief counseling. In addition, physicians treating cancer patients perform an extraordinarily high amount of work outside the patient's presence, including family counseling, telephone calls, arranging for entry into clinical trials, and so forth."

And I don't doubt any of that and I have visited oncologists in my district and I have heard from them and from their staff similar concerns.

Let me actually turn to Mr. Scanlon, and if you will pull the microphone up. I would assume that there are other medical specialties that either provide or would like to provide and be reimbursed for these services. Does Medicare reimburse anyone for these kinds of services in addition to their regular fees?

Mr. SCANLON. Not explicitly. The issue here with oncologists and other specialities, the way that the system has been constructed, is that the costs of these kinds of services to the extent that they are incurred by a practice are included in calculating fees but they are distributed across the procedures and the services that are being recognized by Medicare. This is something that is related to the American Medical Association, which is establishing the CPT, the current procedural local terminology system, which identifies

what are discrete services that physicians are going to provide, and then there is some amendment or modification of those by Medicare. That process is what we need to look at, and as I mentioned, we are doing work on additional data. This is one of the areas where we need additional data. Should there be discrete activities that are now recognized as services and sort of why isn't it that they haven't been identified as discrete services under CPT?

Mr. GREENWOOD. Let me just ask you this. When you came forward with your $51 million estimate to compensate to raise the practice expenses, were you assuming that any of these kinds of services would be included in that?

Mr. SCANLON. We were not assuming they would be included explicitly, but we were assuming that the costs of those services were reflected in the data that we had and that those costs were distributed—$51 million represented distributing those costs more appropriately across different services and across different specialties. So we feel like the data and the method reflect these services, but better data may lead to a different change in fees.

Mr. GREENWOOD. Dr. Norton, your comments.

Mr. NORTON. We don't think they have the data. If they are relying—like the AMA data, there are a small number of oncology practices that were scrutinized and there was a tremendous amount of estimation involved. One thing that makes oncology different from other specialties is other specialties it's some patients that require these services. In medical oncology it's essentially everybody. As the therapies go on, as patients get sicker, as the medicines change, it sometimes gets more complex rather than less. The time the nurse spends with the patient talking about the drugs, talking about the side effects, monitoring for side effects during the infusion and between infusions, this is just essential and it's not covered at all. It's just—and it's not really reflected in the numbers. It's not really reflected in the data because it hasn't been scrutinized carefully.

Mr. GREENWOOD. Let me just bring forth, when we are talking about data here, one piece of data. A recent survey in Modern Health Care estimated that the average oncologist's salary could be as high as $334,000 per year. Is that a figure that you think is within the ballpark, sir?

Mr. NORTON. That sounds high to me, and I've seen surveys of various medical specialties. I don't actually recall the absolute numbers but they varied a lot, again depending upon the sample that was used, the geography, and many other samples. But I do remember that medical oncologists were not outliers in terms of their income by any stretch of the imagination in terms of other medical specialists.

You know, if medical oncology were a very attractive specialty for financial reasons we would have an abundance of candidates. You know, we're having trouble filling our training programs. Everybody who trains medical oncologists is having trouble finding quality candidates for their training programs. It's not a highly subscribed speciality because it is so difficult. It is such a difficult life-style and it's not an especially lucrative life-style either.

Mr. GREENWOOD. Thank you, sir. The gentleman from Ohio, Mr. Brown, for 5 minutes.

Mr. BROWN. Dr. Norton, I have an article from the Journal of Cancer Economics, March, 1997, and I was intrigued by a speech made by a chief medical officer at United Health Care Corporation in Minneapolis to the National Cancer Centers Network, which as I understand the audience is made up of many oncologists and other people. I want to read a little bit from what he said and ask what's happened in the last 4 years. This is March 1997.

He says, "You're going to have to make chemotherapy a cost neutral equation. I would tell you that the industry is probably going to do this for you. Without eliminating the markup on drugs, I really do fear that you are going to lose credibility within organizations outside. Employers are already bringing this up to me. What are you doing about oncologists who are making too much money on drugs? My case managers are coming to see me and saying that about half my patients are dying within 2 weeks of their last chemotherapy course. So where was the oncologist saying it is time for quality of care? Let me give you good supportive care and pain relief. Let me get you into a hospice."

He then goes on to say, "The markups for chemotherapy medicines are going to be so high that the public is beginning to react. You are losing credibility from that," he tells the oncologist. "What you will see happening in my company and I suspect others is that you will no longer be getting reimbursed at average wholesale price."

What you will see happening in my company, and I suspect others, is that you will no longer be getting reimbursed at average wholesale price; you will be getting reimbursed at catalog prices. The reason for doing that is to make this decision truly a decision made, because it's the right thing to do, not because you have a financial incentive.

It sounds to me, from taking these excerpts, that managed care was not going to take it anymore; in a sense, that they were not going to pay you the—they were not going to follow the price structure that Medicare seems to.

What has happened in these 4 years?

Mr. NORTON. No, that's not an individual I know or an organization that I attend. So I don't know exactly what transpired there, what was, you know, sort of implied by all this.

Mr. BROWN. What has happened with managed care payments?

Mr. NORTON. The managed care payments generally are much lower than the actual costs of administration of the therapy. You know, sort of across the board, it really is a big issue.

Mr. BROWN. Lower than Medicare?

Mr. NORTON. I do not know the specifics, sir. I do not know the specifics.

I do know, for example, in my own center that if I didn't have philanthropy pouring into the center, I couldn't provide anyone near the services I provide. I applaud my colleagues in practice, especially small practices, for doing as much as they can with the amount of money that they have flowing in.

Mr. BROWN. So you can't tell me if Medicare—if managed care companies are paying more or less than Medicare?

Mr. NORTON. I personally cannot. I can't provide that information for you in great detail.

Mr. BROWN. Considering the markup, considering if a drug costs $200 and Medicare is reimbursing 1,000 and the oncologist is pocketing some amount of the 800, I would think you'd give us some ball park about what might be happening with managed care companies.

Mr. NORTON. I would challenge the notion of the doctor pocketing the money. The doctor is using that money to take care of the patient. That is what is happening. It is a broken axle and it's a broken wheel. We have to understand the system is working, quality is being provided and the money coming in that's in excess of one side is balancing the other. We've all said the same thing.

Mr. BROWN. I wish you were a little better informed about the managed care side of it, because when I—I go back to Chairman Tauzin's comments earlier about the fact that the copay for many seniors is actually more than the cost of the drug that the doctor is paying. In some cases, that 20 percent is 20 percent of a much larger, huge number in some cases than 20 percent of the real cost of the drug; and I would think maybe if we were able—if anybody on this panel could give us the information about how much a drug—how much the managed care companies were paying, maybe we could help Mr. Scully come up with "20 percent of what" figures, because we don't know. We only know 20 percent of the AWP, but it would be nice to know 20 percent of the lesser figure, and perhaps the managed care companies have alighted on that figure, if you will. But apparently nobody on this panel, with as much expertise as you have, can tell me what managed care has done in the last 3 or 4 years.

Mr. NORTON. I'm not an expert in health economics, frankly. I can get the information for you, and I'd be delighted to work with you on it, but, no, I don't know that.

But I do know——

Mr. BROWN. Would you submit that for the record, please, Dr. Norton?

Mr. NORTON. Any information you need, you ask us, we'll provide.

Mr. BROWN. Thank you.

I'd like to know what managed care companies, versus what—for these 24 drugs; is that it—these 24 drugs, what managed care companies are paying, on average.

Mr. NORTON. As I said, we'll be very happy to cooperate with Congress in every way to give you the information you need.

Mr. BROWN. Good. Thank you.

Mr. EMANUEL. I just wanted to say one thing about the patients and managed care companies.

Almost exclusively, in managed care companies they do not pay a percentage of the drug, right, almost exclusively in managed care companies. If Medicare is going to look like managed care companies, they are going to have a fee schedule that is like $5 and $10, independent of the price of the drug. Okay? That is the way managed care companies are run now.

Now, they may be shifting because of rising prices——

Mr. BROWN. If I can interrupt, Dr. Emanuel. I don't think that—because Medicare doesn't have much of a track record of paying for drugs. Only these drugs that—and it's such a peculiar way you do

it. I don't know how you can say that Medicare will set a price and it's irrespective of the price that the drug actually costs.

Mr. EMANUEL. That is not what I said. Sorry. Maybe I was unclear.

Mr. BROWN. Tell me again. I'm sorry. I misunderstood you.

Mr. EMANUEL. In managed care, patients are—they have copays of $5 and $10. They are unrelated to the price of the drug.

Mr. BROWN. The copay?

Mr. EMANUEL. And Medicare is different in that it makes the copay related to the price of the drug.

If you want to make Medicare like managed care, then you fix the copay independent of the price of the drug.

Mr. BROWN. I didn't say I wanted to make Medicare like managed care in that way.

If, in fact, managed care has done what this article might suggest it will have done in the next couple of years, starting back 4-plus years ago, then we might be able to use that as a real price for these drugs. If that, in fact, is what these drugs cost from the manufacturer that managed care is paying for, then we might be able to talk more about Chairman Tauzin's 20 percent of that figure rather than 20 percent of the AWP figure.

Mr. EMANUEL. I'm not an expert on managed care pricing either, but let me just say one other thing.

One of the problems is that if you go to managed care and talk to them—and one of the other things I do in my head is talk to them about these things—they don't have a price for the drug. Just like manufacturers play around with prices to doctors and to pharmacies, they play around with drugs to managed care, so if you buy three of our drugs, we'll give you this kind of discount.

If you're only putting one on the formulary—so there is no such thing as "the price of a drug."

Mr. BROWN. We know that, and particularly when—in light of the fact that Americans, out of pocket, pay about twice as much as what managed care companies on the average pay for the cost of prescription drugs.

So, so be it. Thank you.

Mr. GREENWOOD. The time of the gentleman has expired.

The gentleman—the chairman, Mr. Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman.

Dr. Norton, let me see if I can help understand this a bit better, and maybe you can give us some history—a bit. In terms of the way the different physician groups negotiate with CMS, formerly HCFA, for their reimbursement for practice expenses, would oncology groups actually go in and make a case for the—all of the expenses you indicated were not now covered?

Mr. NORTON. Absolutely for——

Chairman TAUZIN. Have you made that case over the years?

Mr. NORTON. If we are asked to. We have offered it. We have offered to do that, and they have said that we'll call you when we need you, but we are still waiting for the phone call.

Chairman TAUZIN. You've never had the opportunity to make a case on what your true practice expenses are?

Mr. NORTON. That is exactly right.

Chairman TAUZIN. So are you telling me that HCFA, in the past, was just not interested in hearing from you on those numbers?

Mr. NORTON. Again, what CMS or HCFA previously has done is—you know, they will have to tell you that.

I do tell you, we are very anxious to help in trying to determine these costs. We have offered it, and we've been told that we will be called when they need us.

Chairman TAUZIN. Staff is advising me that every physician group has the right on a yearly basis to submit data to refine the practice reimbursement costs. Have oncologist groups taken advantage of that opportunity under the law?

Mr. NORTON. The—my understanding is that it's done sort of collectively, but that oncologists are clearly, you know, part of a very large number of physicians that—you know, that do this. But my organization, ASCO, the American Society of Clinical Oncology, has offered on many occasions to help in determining these costs, and we're still very willing to do that.

Chairman TAUZIN. Mr. Scanlon, you're here. Could you help us with that process?

I mean, my understanding is that every group can come in every year and do that. If Dr. Norton has said they really haven't had that opportunity, I'd like to know why not and what's wrong with the process.

Mr. SCANLON. Groups do have the opportunity to come in individually. There has been additional information that's been incorporated in the practice expense that comes from the American Medical Association's survey of all specialties, but individual specialties—and thoracic surgery is one that has submitted data of its own—it involves doing a survey of its practices.

Chairman TAUZIN. So they weren't invited to do it? They did it on their own?

Mr. SCANLON. Congress gave them the right to do this in the Balanced Budget Reform Act.

Chairman TAUZIN. So the question, Dr. Norton, is why haven't oncologists on their own submitted data to have the——

Mr. NORTON. We have offered and we have been told that we will be contacted when it's appropriate for us to give the information; and we're still willing.

Chairman TAUZIN. What I'm hearing is that you don't have to offer to do it. You have a right to do it. You don't have to have an invite from them. You don't have to make an offer that is accepted. The law says that every year every specialty of practice has a right to submit new data, revised data, to ask the agency to revise the reimbursement under the pool. And my question is, why haven't you done that?

Mr. NORTON. We have had contact with numerous agencies, and we've offered our assistance in determining these prices. There's issues in costs, in fact.

Chairman TAUZIN. Well, you tell me what you did, but you're not telling me why you didn't do what you could do. So let me say it again as clearly as I can.

If you have the right to submit it without an invitation, if the law gives you the right every year to go to CMS now and say, these

are our numbers on what it takes to properly reimburse us for practice expenses, why haven't you done that?

Mr. NORTON. Well, part of it is that it's an expensive proposition to do it properly, frankly. It's—we are a voluntary organization, and it's a very expensive proposition to do that.

Chairman TAUZIN. But I don't understand that. If you're being so underreimbursed, why would—if other companies have done that, why wouldn't you do that?

Mr. NORTON. You know, we didn't create AWP; we inherited AWP. You created AWP, and the fact is, it's been working. It's a broken axle, broken wheel, but it's been working.

Chairman TAUZIN. I thought that was the answer, because that is our suspicion. The reason why we've never gotten a real definitive, you know, resolution of what the true practice costs are in some of these fields is that you felt comfortable with the AWP reimbursement as taking care of whatever deficiencies exist. Right?

Mr. NORTON. We haven't felt comfortable with AWP. We've been opposed to the whole concept ethically, morally.

Chairman TAUZIN. I'm just saying in terms of the dollars.

Mr. NORTON. The economics have worked. We're able to keep the ship afloat.

Chairman TAUZIN. So that if you didn't have the advantage of the overreimbursements under AWP, you would probably be more likely to do what other specialty groups have done every year, and that is get in there and pitch a case for why you want to be reimbursed more thoroughly for your practice expense?

Mr. NORTON. We absolutely would help determine the proper reimbursement, absolutely.

Chairman TAUZIN. Now, recognizing that that hasn't happened and recognizing that if we do eliminate this practice of overreimbursing for drugs, which some specialty groups, like your own, have relied on upon rather than seeking changes in that pool, if we did that, you would—is there any doubt you would head straight to that pool and seek a reassessment of your practice expenses?

Mr. NORTON. Oh, we would like to work to make a fair cost. Absolutely. Sure.

Chairman TAUZIN. And would it be helpful if we had your cooperation and the cooperation of other groups, specialty groups, affected, in eliminating this practice of the AWP—because it has other pernicious effects, not just this financing thing—if we got rid of it, would it be helpful if we asked you to work with GAO and the IG and Scully and our own committee to determine what is, in fact, a fair estimate of what practice——

Mr. NORTON. It would not only be helpful; it would be wonderful. We would relish that opportunity.

Chairman TAUZIN. If we told you in advance that we were prepared, and this committee was able, to support additions to the fund so that, in fact, there would be less pressure on you having to go get your dollars from some other practice group, but there would be room to make up a reasonable—in a reasonable way, commensurate with what other practice groups are getting—I'm not saying that we should favor one practice group over another in that process, but to give more room for you to adequately get a reevaluation of your practice——

Mr. NORTON. See, again——

Chairman TAUZIN. Would such a proposal meet with your support?

Mr. NORTON. Yes. It sounds great. Frankly, you know, the point is that we're not talking about consultation costs or visit costs. We're talking about actually—the cost of actually treating patients, the cost to treat patients. Any solution that enables us to be able to continue to treat our patients is a solution we'd be happy——

Chairman TAUZIN. That is the solution we want. When we started this discussion, the chairman will tell you we had briefings, and I, among a number of members, made it very clear that if we're going to do this, if we're going to take this on, this massive project to change this, when 10 years have gone by and nobody could do it, that the one outcome we could not have is that somehow you were not going to be out there taking care of cancer patients as a result. And then that's your leverage in this thing. We understand that.

But our leverage is that—I want you to understand this. Our leverage is that I don't think patients in America, upon learning that they're paying a 20 percent copay that is equal to 500 percent of the cost of a drug that the doctor buys—I don't think patients in America are going to let anybody put up with this system, now that that's out in the open; and that patients are gradually going to understand how bad that is.

I mean, when my 82-year-old mom hears that she has to pay a 20 percent copay that's equal to five times what the doctor is charged for the drug, I can tell you, I'm going to get a few phone calls from that lady, and I suspect every Member of Congress would. And if there were a legislative stand-alone proposal to change that, it probably would zip through this Congress.

So I guess my message is that we understand, I think, the problem of how we've gotten in this mess. I also want to say this again. I think you're the angels sent from God for the work you do, and I know why you're having a hard time recruiting in some cases.

It's so awful to watch people go through what people go through in cancer, and you guys do it all the time, and I admire you so much for that. I want you to understand that.

We understand the problem you're in, but we need your help to fix it. And if we're going to come up with a formula that works, we're going to need all the specialty groups working with us to come up with a solution that answers it. If we don't, we're going to end up having to sell parts of it at a time, like this 20 percent copay thing, and that's not going to be good. That's just going to take a chunk out of income.

But, in fairness, I can't see asking my mom or anybody else to pay 500 percent for some—for the cost of some drug, when the law says they ought to pay 20 percent of it. There's something wrong there.

Bottom line, I guess what I'm saying is, I think we're seeing our way to some solutions, but we're going to need the support, help and encouragement of the provider groups, such as yours, in finding it in a way that you continue and can continue to serve America's cancer patients; and at the same time that we can put an end

to this system, not simply because it may be wrong financially, but because it has some potential aspects to it that are so disturbing.

To think that the bonus paid for chemotherapy might encourage anybody to use it when it's not appropriate is just an awful thought, and I hope it does—I hope it is not happening in America. But the thought that it could is just so disturbing, that I think we have to—we have to deal with this pretty soon.

And so, again, thank you for your contributions today, all of you, and I hope we—I want to do one more thing, if I can, Mr. Chairman. I want to turn to Dr. Emanuel.

What is a nonresponsive chemo situation? You named a bunch of cancers. Tell us what that means. That means that chemo doesn't help at all?

Mr. EMANUEL. Right. The chemotherapies we have available do not shrink the cancers.

Chairman TAUZIN. Do they help with the patients in any other way?

Mr. EMANUEL. Usually they are not recommended when they don't shrink the cancer.

Chairman TAUZIN. Well, that's what I'm having a hard time understanding. Why in the Massachusetts study did you—and maybe, Dr. Norton, you can help me.

Mr. NORTON. I can help you.

Chairman TAUZIN. Why did you find that doctors were doing chemotherapy on patients when chemotherapy was known not to work?

Mr. NORTON. Generally speaking, we define "responsive" as about a 20 percent response rate. But somebody who is desperate will take less than a 20 percent response rate, and that's—frankly, I think it's one cycle. You say, Listen; the patient says, Listen, Doctor, please try.

Chairman TAUZIN. Very often, it's a patient saying, I don't want to——

Mr. NORTON. I spent 45 minutes with the daughter of a patient this morning before I came here. She was begging me to treat her mother with chemotherapy, and I frankly said I didn't think it was appropriate.

Chairman TAUZIN. So I just——

Mr. NORTON. One cycle is what Dr. Emanuel found in his study. You know, when a patient comes in, desperate, and says, Please try; and you can find in the medical literature 5, 10 percent response rates in all these diseases to various—you say, We will try one cycle; if the cancer doesn't shrink, we will stop. And frankly I don't think that is so unreasonable. You know, you say the last 6 months, the last 3 months of life; you don't know that until a patient has died. If they respond to therapy, it's no longer 3 months.

Chairman TAUZIN. I'm trying to help you. So the fact is that the bonus that exists in this reimbursement system may not be the reason why even in a nonresponsive cancer case chemo is selected, because the patient may want it in some cases.

Is that right, Dr. Emanuel? Do you agree with that?

Mr. EMANUEL. Yes. I think that's—we've all experienced that situation.

Chairman TAUZIN. Thank you very much, Mr. Chairman.

Mr. GREENWOOD. The gentleman's time has expired.

The gentleman from New York, Mr. Engel, is recognized for 5 minutes.

Mr. ENGEL. Well, thank you, Mr. Chairman.

If this was another hearing in talking about Medicare and reimbursements and what Medicare pays for, I'd be talking about how Medicare can pay for syringes but not for the drug insulin to—which is used in the syringes. I'm constantly confused by what goes on.

But since we're talking about home infusion, infusion therapy, I want to talk a little bit—and I thank you, Mr. Connaughton, for mentioning it in your testimony. I want to highlight my bill, which is H.R. 2750. We called it the Medicare Home Infusion Therapy Act, and what it does is it addresses the particular problems associated with home infusion therapy.

Medicare's reimbursement policy for home infusion therapy is simply outdated. Modern medicine has made the administration of many drugs safe and effective in the home. Because of these ridiculous reimbursement provisions, many senior citizens are forced to stay in hospitals or trek to physicians' offices on a daily basis to receive their treatment, when this treatment can be given to them in their homes.

It's much cheaper. It's much easier for everyone around, and yet we can't do that. It can be conducted in the home safely, and it could be at a fraction of the cost.

So, to address that issue, the bill directs the Secretary of Health and Human Services to set up a fee schedule for drug reimbursements and provider reimbursements that would ensure adequate and fair payments to providers. I very strongly feel that this legislation appropriately addresses the needs of seniors and providers together and could serve as a model for a broader approach to the problems with AWP, and I'm hoping that we as a committee will examine the legislation.

Mr. Connaughton, since you mentioned it, I'm wondering if you could expand on some of your remarks, because as I mentioned, the bill doesn't only reform how currently covered home infusion drugs are regulated, but it would also extend coverage to drugs that are not currently covered, such as home antibiotic therapy; and I wonder if you could just talk about that expansion. And what do you think this bill would do for Medicare beneficiaries?

Mr. CONNAUGHTON. Let me just make a couple of comments.

First of all, I think your bill is absolutely consistent with the five principles the chairman enunciated earlier when he was speaking with Mr. Scully. Medicare, as I've mentioned in my testimony, is losing the advantage of infusion therapy in the home. The coverage by Medicare for home infusion is extremely narrow. Managed care is taking advantage of that opportunity, and indeed Medicare's use of home infusion is less than 20 percent of what home infusion companies do.

There are many therapies that are not covered by Medicare now that could be covered by Medicare and are covered by managed care in the home. It would make tremendous savings.

The key to your bill I think, Mr. Engel, is that it spells out a reimbursement scheme and recognizes that these services are a value

in the home, but it spells out a reimbursement scheme that is based upon costs of a product and the costs of the services and recognizes that there are standards for those services that are recognized in the private sector; and we think it's a very, very good piece of legislation.

Mr. ENGEL. Thank you.

Let me ask you this: If Medicare were to adopt the same quality standards that are used in the private sector, how do you think this would affect the care provided to Medicare beneficiaries?

Mr. CONNAUGHTON. Well, it would ensure they are getting the same quality of care that they're getting in the private sector. In the private sector there are standards; they spell out the services. Medicare, for whatever reason, just does not recognize that these services exist; and I think it's important for them to recognize them and spell out the standards.

Mr. ENGEL. And as things have evolved in health care—obviously, when Medicare was first put into place, we couldn't have anticipated the changes and the improvements we've made, and therefore I think it's fair to say—and I'm sure you would concur—that we need to change some of the—to update, I think that's a better word, some of the procedures that we have now.

Mr. CONNAUGHTON. I would agree with that.

In the case of home care, technology is going to allow us to do a lot more things. Infusion therapy is a current issue, but I hope over time that Medicare will be able to take advantage of those technologies.

Mr. ENGEL. Now, I want to make sure that I understand something you mentioned earlier. I think the chairman also—I'm sorry. Mr. Brown, I think, mentioned it before.

The costs of acquiring the drug for home care suppliers are in many cases less than the cost of administering it.

Mr. CONNAUGHTON. That's the case. On average—it varies from therapy to therapy, but on average, our survey that was conducted, about 26 percent of the cost of providing the therapy is the drug.

Mr. ENGEL. So obviously that is something we need to fix. I'm sure that's why Mr. Brown mentioned it, and I think it's something that the committee ought to look at.

I'm wondering if anyone else would want to comment on that. Yes.

Ms. LAMPHERE. Indeed, the services that you were talking about and the quality standards that you were talking about are very important. The nursing coordination, the patient education, the pharmacy operations, all of these direct services, at least in the case of home infusion and respiratory therapy, account for 46 percent of the total cost of providing respiratory and home infusion services in the home.

Mr. ENGEL. Yes. I think that's a shocking statistic, and I certainly think it shows that things are broken and need to be fixed. I thank you.

Thank you, Mr. Chairman.

Mr. GREENWOOD. I thank the gentleman.

The gentleman from Iowa, Mr. Ganske, for 5 minutes.

Mr. GANSKE. I thank the members of the panel for staying for a long day.

I think that there's been a consensus today, from the previous participants, that the way that we've calculated reimbursement for drugs and Medicare needs to be made more accurate, and that we need to take into account the true costs of the administration and the services to get those drugs to the patients. And I think your testimony has been effective. I thank you and I yield back.

Mr. GREENWOOD. The gentleman, Mr. Norwood for 5 minutes.

Mr. NORWOOD. Thank you, Mr. Chairman. I will be relatively brief, but I'm interested in a couple of things.

Dr. Norton, you listed in your testimony a number of services that clearly the oncologist has to perform for the patient if they are to get good care. Those services presently are not recognized by Medicare.

Mr. Scanlon, I'm curious, since the GAO seems to know a lot about this subject, why aren't—well, let me go back a minute. You said, "not explicitly." That means no, I gather.

Mr. SCANLON. No, it doesn't. Excuse me. Not recognized, but paid for. And the difference is that the way that Medicare practice expense fees are determined is that all the costs of the practice are taken into account, so presumably these kinds of activities generate costs which are carried on the books; and those should be taken into account when practice expense payments are determined.

Mr. NORWOOD. Dr. Norton, do you believe that that is actually the case?

Mr. NORTON. You know, I am an expert in statistics; that, I am, even though I'm not an expert in economics. And my understanding is that the methods that are used to actually make these determinations are filled with approximations. It's approximation upon approximation—approximation of expense, approximation of time, calculations, multiplications of submitted procedures and various percentages.

I question, just as a scientist—and I'm not an economist. As a scientist, I question the validity of some of these methods, frankly.

I would like to see a method that starts with the actual procedure and builds up and calculates the cost on that basis. You know, if it's going to be a half an hour of somebody's time to talk to a patient, then it should be a half an hour of this hour that's reported into the equation, and that's the way it ought to be calculated.

If we do it that way, we very well might come up with a different number. And I'm not even saying that I know for sure we'll come up with a different number. I just think that the science of actually coming up with the cost estimates could be improved.

Mr. NORWOOD. Well, Mr. Scanlon, and then you.

It appears that the providers of this care, though their services aren't listed, feel that they aren't compensated. That's fairly clear to me.

Now, Mr. Scanlon, I presume that a lot of your numbers are the result of estimations.

Mr. SCANLON. The numbers are based upon samples, samples both of the practices in terms of reporting their actual costs that they incurred; and then panels of experts that were put together, doing what Dr. Norton suggested, which is to take for each procedure and to say, this is our estimate as to how much nurse time,

how much other staff time, how much supplies, et cetera, it takes to provide that procedure.

The flaw that was discovered in that method is, when you add it up, for all of the times and all of the different costs that the panels had, they didn't match the data that the practices were actually writing checks for. And that's why it was critical to bring both of these pieces of information together.

Think of it in terms of, if we were all asked to tell everyone how we spent yesterday, give every activity that you were engaged in and the amount of time, it might not add up to 24 hours, but there were still only 24 hours in yesterday. And the problem is, it's very hard in the abstract sense to say this is going to take 50 minutes, this is going to take an hour, et cetera. So the data of costs that practices actually incur is a very good and strong benchmark in terms of being able to calibrate these expert panel estimates.

I agree with Dr. Norton, in a sense, that the data need to be improved. We need to get data that are going to be more robust, have smaller variance in terms of the estimate of the true values. I don't agree that the method is invalid.

The method is valid. We just need better information with which to execute it.

Mr. NORWOOD. Well, isn't it then true that perhaps the reason we are having this hearing is, the data is not robust, as you put it? As far as I know, the oncologist did not come up with a plan for how to be reimbursed in terms of the cost of drugs. I presume that our old agency, HCFA, dreamed that up.

Mr. SCANLON. There are two elements; I mean, in terms of why we may be having this discussion. One is data, and we—and I've talked about that. The other that I mention in my testimony is the fact that the method that I'm saying is valid, the method I think that needs to be applied for all specialties, is not the method that was used to calculate the fees for chemotherapy administrative services, as well as for other services where there's not direct physician involvement.

We believe that CMS needs to calculate all fees, using what we've referred to as the basic method, which in our mind, appropriately allocates total practice expenses across the procedures that specialties have, takes into account to the greatest extent possible differences in the costs of delivering a service by one specialty versus another.

Oncology, again, is affected by what HCFA did in the past. It took the chemotherapy administration services and put them in a pool with all other similar types of services from other specialties and calculated fees on the basis of that average. We don't think that is appropriate.

So if we were to apply the method appropriately, we would get a different result. It's the chemotherapy fee—administration fees would change 16 percent; overall fees to oncologists would change 7 percent. So those are the kinds of things that we have been talking about.

Mr. NORWOOD. Dr. Norton, I heard Chairman Tauzin say that he knew that Mr. Scully would be greatly interested in your organization's input, and I know you're interested in doing that. You're president of your society, are you not?

Mr. NORTON. That's right, sir.

Mr. NORWOOD. How many members do you have?

Mr. NORTON. About 17,000.

Mr. NORWOOD. American Society of Clinical Oncology.

What is your pay as president?

Mr. NORTON. Oh, I don't get any pay at all. This is voluntary. My institution gets some money—I actually don't even know the amount—to compensate partially for the time I spend. But since I spend essentially 100 percent of my time doing this job as well as 100 percent doing my other job, it's nowhere near compensation. I receive no funds whatsoever.

Mr. NORWOOD. So I want to point out to our chairman that you are a volunteer organization, and sometimes it is not as simple as it seems when a voluntary organization is asked to defend itself against a Federal organization—a Federal agency that has thousands and thousands of employees who sometimes don't get in a hurry.

I may be wrong about that, but a lot of times it's very difficult on the other end to do what we're asked to do.

And I don't frankly understand, for example, why CMS doesn't list the services and determine, with the help of people like Dr. Norton, what a fair, reasonable fee is, and make it so much simpler for everybody; rather than putting the onus on the back of a volunteer organization, oh, it's all your fault because you're not being reimbursed.

I know I'm running out of time. I've got two quick things, Mr. Chairman, if I could finish.

Mr. Scanlon, just yes or no. Do you happen to know, is it GAO that told President Johnson that the cost of Medicare in 1990 was going to be $9 billion?

Mr. SCANLON. No.

Mr. NORWOOD. Okay. Just checking. I know one of the agencies did. I just can't remember which one.

Dr. Emanuel, God forbid if you should ever have cancer, where would you choose to be treated?

Mr. EMANUEL. Think it depends on the kind of cancer. I would try to find the right oncologist for the cancer.

Mr. NORWOOD. Would you prefer to be treated in the United States?

Mr. EMANUEL. Well, certainly compared to other—certain other countries which are struggling.

Mr. NORWOOD. You implied that our oncology care in America is pretty poor and listed reasons why you thought perhaps they were poor, and I wondered if that's what you meant to imply.

Mr. EMANUEL. No. I think what I said, or certainly what I meant to say, is that we at this moment cannot guarantee every American who has cancer the highest quality oncological care for that cancer. We know that there are problems. We know that there is underuse and we know that there is overuse, and part of the issue is to make sure that we can guarantee everyone that they get the right care at the moment.

Mr. NORWOOD. We can't guarantee everyone we can stay out of the way of an airliner. How can we guarantee everyone?

Mr. EMANUEL. Well, we don't even have a monitoring system to make sure that Americans do——

Mr. NORWOOD. And who do you want to determine who gets the care, if you don't want the people who are trained in oncology to determine it?

Mr. EMANUEL. I think we need——

Mr. NORWOOD. Some oncologists decided a patient shouldn't get the treatment, or should. Okay. If you don't like them deciding, who do you want to decide?

Mr. EMANUEL. I'm—at the moment, I certainly think oncologists have to be part of it. I'm actually at the moment the head of the ASCO Task Force on the Quality of Cancer Care. One of the things I think we do need is to have a monitoring system to make sure that people who are diagnosed with cancer get referred to the right person, get the right procedures, not too much and not too little, and who——

Mr. NORWOOD. Who is "we"?

Mr. EMANUEL. I think that's a collective responsibility, and as a matter of fact, ASCO, the American Society of Clinical Oncology, has undertaken a $5 million study to try to find out where the flaws in the system are. We know that there are flaws in the system and that it's not working perfectly; and I think it would be wrong at this point in time to say, just because I'd like to be treated in the United States, that we have a flawless system.

We know we have quality problems, and we know we need to have oversight and to improve the quality of cancer care delivery. The issue is, where are the problems, how can we monitor them, and how can we collectively—oncologists, the government, nurses, hospitals, insurers—improve that system.

Mr. NORWOOD. I see the red light, Mr. Chairman.

Mr. GREENWOOD. The time of the gentleman from Georgia has expired. I thank the gentleman for his questions, and let me advise the gentleman from Georgia that it is my intent, in the legislation that we introduce, to fix this problem; that we will, in fact, direct CMS to do the work with these associations, but certainly to provide the technical support so that we can develop the data, so that they are adequately compensated. And that will not be a burden placed on the backs of the voluntary organizations exclusively.

Mr. NORWOOD. And, Mr. Chairman, if the organization has a white paper on—at least their opinion on how to go about fixing the problem, shouldn't at least CMS have a white paper on how they think the problem ought to be fixed?

Mr. GREENWOOD. Well, we're going to make them work so fast that they won't even have time for a white paper.

The Chair asks unanimous consent to submit for the record the following documents: two volumes of committee documents; the opening statements of—the statements submitted by Congressman Stark and other members' opening statements; two letters to the committee from U.S. Oncology, clarifying the documents obtained by the committee.

And I would ask unanimous consent that we hold the record open for members to submit questions.

With that, we thank the final panel for your testimony, for your presence, for your endurance as well. This committee does intend

to fix this problem. We intend to fix it in short order. We intend to fix it rationally and fairly for the benefit of the taxpayers, the beneficiaries and the valued health care providers. Thank you.

The committee hearing is adjourned.

[Whereupon, at 3:15 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

STATEMENT OF
CONGRESSMAN PETE STARK
FOR THE SUBCOMMITTEES OF HEALTH AND OVERSIGHT AND INVESTIGATIONS
OF THE HOUSE ENERGY AND COMMERCE COMMITTEE
Joint Subcommittee Hearing on
Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers
September 21, 2001

GAO Investigation Proves Major Drug Companies Have Abused Medicare and the Public through Distortions of the Average Wholesale Price; Recommends Scrapping the AWP

Congratulations to the General Accounting Office (GAO) and the Health and Human Services' Office of the Inspector General (IG) for their outstanding work in exposing the abuse of Medicare beneficiaries, the public and private health programs by some of the nation's leading pharmaceutical companies and some physicians. These investigations leave no doubt that drug manufacturers inflate the Average Wholesale Price (AWP) of their products in order to bribe physicians to prescribe their drugs.

The investigation confirms what many of us have been saying for years. Pharmaceutical companies manipulate the AWP to increase profits, which increases costs to patients and taxpayers by influencing physician-prescribing practices. This raises serious questions about the legitimacy of Medicare spending in this area, and, even more importantly, the quality of treatment and whether patients are being prescribed the right drugs. Previous evidence has shown that patients may be given inappropriate drugs as a result of the financial incentives in the current system.

I have introduced legislation in the past to stop these abusive practices, and the previous Administration had also tried to put an end to this policy. Numerous lawsuits have been filed on this issue and at least one has been settled this year alone. The evidence against the manufacturers and others involved in this scheme is overwhelming.

According to GAO, the AWP is 13 to 23 percent greater, on average, than the actual costs charged to physicians. In some cases, the spread between the AWP and actual costs is as much as 65 percent and 86 percent. As we have longsuspected, this

translates into unjustified, higher costs for Medicare, the taxpayers, and Medicare beneficiaries and it should be stopped.

I've advocated for years that we move toward a system based on acquisition costs. Now GAO is further substantiating the need to take immediate action to fix the widespread abuse of the AWP system. The integrity of federal health care delivery depends upon it. According to the IG, AWP abuse increases costs to beneficiaries and Medicare by up to $1.9 billion annually. Because beneficiaries pay 20 percent co-insurance on covered Part B services, this means that America's senior citizens and disabled persons who use these services are overpaying by nearly $400 million each year. Given that very few outpatient drugs are even covered under Medicare, it is simply unconscionable that these beneficiaries, and the taxpayers, are not getting the best possible price.

The GAO investigation and recommendations should stop any efforts by special interest groups or Members of Congress to block efforts to implement long-overdue remedies. I couldn't agree more with GAO's recommendation to scrap the AWP in favor of a system that reimburses drugs at levels that reflect actual market transaction prices. Doctors should be reimbursed for their actual acquisition costs. This measure would eliminate the abuse of AWP and would also contain the ballooning costs of prescription drugs.

Certain physicians will not be pleased with the findings of the IG and GAO. They will try to frighten beneficiaries into thinking that efforts to stop AWP abuses will curtail beneficiary access to physician-provided drugs. That is nothing more than a cynical scare tactic to persuade beneficiaries to support a system that forces them to pay more in order to pad physician income.

Furthermore, physicians should not profit on drug selection. A forthcoming GAO report will examine the adequacy of physician payments for certain activities. If it shows, as we anticipate, that physician fees should be adjusted for certain services, then those payments should be adjusted accordingly. However, that need doesn't support continuance of this corrupt system that rips off Medicare and patients.

The timing of this investigation is particularly important in view of the current debate about adding a prescription drug benefit to Medicare. Prescription drugs are an integral part of medical treatment today and Medicare must be modernized to include them. However, as the largest purchaser, Medicare should not and cannot afford to be paying top dollar for drugs. That is why the AWP should be abolished in favor of a pricing system that guarantees seniors affordable access to covered prescription drugs.

September 19, 2001

SENT VIA FACSIMILE TO (202) 225-1919

ATTN: Tom DiLenge
Counsel, Subcommittee on Oversight and Investigations
House Committee on Energy and Commerce

The Honorable James Greenwood
Chairman, Subcommittee on Oversight
and Investigations
U.S. House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office
Washington, DC 20515

Dear Chairman Greenwood:

Thank you for your willingness to work with US Oncology, Inc. (USON) as part of the House Energy and Commerce Committee's efforts to reform the Medicare program's reimbursement of oncology drug and practice expenses.

USON provides comprehensive management services to community-based oncology practices across the nation. As a management services provider for community-based practices, USON does not actually receive any reimbursement from Medicare or any other payor, but is able to aggregate relevant information from its affiliated practices. In this capacity, USON is able to assist the Committee as the Committee assesses Medicare reimbursement of oncology drugs and practice expenses.

In responding to your letter of September 14, 2001, please be aware that the information below is what we have been able to assemble in the time frame provided. To the extent additional information is needed, USON stands ready to continue its work with you and your staff to answer any questions the Committee may have. Accordingly, the following information is submitted for your review:

Describe the methodology employed by Ernst & Young in calculating the cost of pharmaceutical purchases by USON, including whether the auditors accounted for

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grants, sponsorships, rebates, free goods or other off-invoice discounts in determining such costs.

Background and History: To effectively describe the methodology used in the USON study, a brief history of USON's involvement in this initiative may be helpful. USON and its affiliated cancer caregivers have long maintained that the Medicare program's reimbursement of oncology drugs and practice expenses is flawed: While reimbursement for oncology pharmaceuticals is too high, reimbursement for practice expenses is too low. Moreover, we recognize that any reform effort that focuses only on reducing pharmaceutical reimbursement, without considering practice expense reimbursement, would significantly undermine the ability of oncologists to provide cancer care to their patients. To that end, USON has advocated for some time that Medicare reform is needed:

- In the beginning of 1999, USON (then known as American Oncology Resources, Inc.) first briefed the Subcommittee on Medicare's reimbursement of oncology drugs and practice expenses.

- In 1999, USON sponsored, with other participants in the oncology community, a study entitled, "The Impact of Medicare Payment Policies on Patient Access to Quality Cancer Care" by Barton McCann, M.D. and Julia A. James. This study described oncology drug reimbursement and practice expenses and for the first time ever quantified the extent of the drug overpayment at the physician level.

- In 1999 and 2000, USON actively worked for a GAO study of Medicare's reimbursement for pharmaceuticals and related practice expenses. USON then met with the GAO to offer assistance with its study.

In offering our assistance to the GAO as it undertook its BIPA-mandated analysis, we noted that USON's position enabled it to assemble data regarding Medicare's reimbursement for pharmaceutical and related drug administration services for affiliated practices. We also noted, however, that USON's network of affiliated practices recognizes a number of efficiencies not obtained by most community-based oncologists. Further, we explained that approximately 80% of cancer care is delivered in community office settings and that it is our understanding that the typical oncology practice consists of 3-5 physicians. Thus, we cautioned the GAO that information we provided would not be representative of the experience of most small, community-based oncology practices and that the Health Care Financing Administration (now known as the Center for Medicare and Medicaid Services) should be tasked with a definitive analysis of this complex set of issues.

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Study Objective and Methodology: After discussing these issues with the GAO, we undertook what we believe was the most comprehensive study possible in the GAO's nine month time frame. The sole objective of the study was to analyze the Medicare program's reimbursement to USON's affiliated practices for the year 2000 for pharmaceuticals and related administration services, and the expenses incurred by the affiliated practices for those drugs and their administration.

To achieve this objective, USON established financial procedures designed to report the experience of those affiliated practices, on a consolidated basis, relating to revenues and expenses for drugs and drug administration. The procedures (described in detail within the Ernst &Young (E&Y) reports and in USON-supplied flow sheets and narratives reviewed with the GAO and the Committee) were designed to:

(a) Consolidate the practices' direct and shared expenses;

(b) Allocate these expenses to the drug and drug administration categories of services;

(c) Apply the expenses related to the provision of drugs and drug administration services to Medicare beneficiaries; and

(d) Calculate the reimbursement received from Medicare for these products and services.

As part of this procedure, USON applied actual utilization data based on products and services provided, as well as actual drug costs (i.e., net of all rebates and all discounts). The information compiled by USON is truly reflective of the costs incurred by USON's affiliated practices in their purchase of pharmaceuticals. These costs include all price concessions (e.g., discounts, rebates) relating to the purchase of pharmaceuticals. As an aside, it is USON's policy that affiliated practices not accept free goods as part of purchasing contracts, other than the drug replacement programs provided to affiliated practices by pharmaceutical companies for the practices' provision of care to indigent and uninsured patients. The provision of free goods for indigent patients is monitored as part of our comprehensive compliance program, and our policy on that topic is attached (Attachment A)

(a) **Items Excluded from the Analysis.** In performing the analysis, USON excluded those items not related to pharmaceutical or pharmaceutical administration revenue or expenses. These exclusions fall into two categories: (i) revenue and expenses that would not meet the test for inclusion in a Medicare cost report process for hospitals (given that USON, as described to GAO, attempted to emulate the "Part A" cost report process in our compilation), and (ii) USON revenue and expenses independent of our relationship, and thus not shared, with our affiliated practices. For example,

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the amortization of intangible assets, general development, corporate planning and directly associated marketing costs and nonrecurring costs as well as revenues and expenses from USON's separate clinical research and educational, communications and marketing service programs. If these excluded items were included, then the net income in the compilation would be reduced by approximately $13 million.

(b) **E&Y's Role.** USON retained the independent accounting firm E&Y to perform "agreed upon procedures" according to guidelines established by the American Institute of Certified Public Accountants Auditing Standards Board. As USON has consistently and repeatedly stated to the GAO and the Subcommittee, E&Y was not engaged to, and did not, perform an audit. In two reports, E&Y recomputed calculations performed by USON when USON calculated the costs and reimbursements for Medicare-covered drugs and related practice expenses. The results of E&Y's calculations agreed with the results of USON's calculations. Copies of USON's study, together with E&Y's reports and other relevant information, are attached to this letter. (Attachment B) As noted above, this information previously was supplied to the Subcommittee.

Other Relationships with Pharmaceutical Companies: In addition to the purchasing relationship that USON has on behalf of its affiliated practices with pharmaceutical companies, USON maintains two other principal relationships with pharmaceutical companies, each of which is operated separately from the purchasing activities. First, USON provides comprehensive FDA-audited services to practices engaged in clinical cancer research with pharmaceutical companies, from study concept and design through regulatory approval, including complete Phase I through IV capability. USON currently supervises 98 clinical trials, with annual accruals of more than 4,000 patients. In this capacity, USON has played a pivotal role in bringing nine new pharmaceuticals and therapies to the market, thereby significantly benefitting cancer patients. It is important to note that research activities are generally conducted at a cost -- not at a profit -- to USON. In 2000, USON subsidized research activities, at our expense, in the amount of approximately $530,000.

Second, USON provides educational, communications and marketing services in the oncology community. As part of these services, USON organizes and facilitates conferences and electronic media communications among pharmaceutical companies, oncologists, oncology nurses and cancer patients. The educational, communications and marketing services to pharmaceutical companies include:

- Opportunities to make presentations, both at organized conferences and through electronic media, to oncologists and oncology nurses regarding new clinical and scientific developments (in accordance with the Prescription Drug Marketing Act

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and continuing medical education accreditation standards established by the American Medical Association);

- Continuing medical education (CME) training courses;
- Organizing conferences for cancer patients (the description of a recent conference is attached hereto. (Attachment C)

Fees received by USON from pharmaceutical companies and other vendors for these services were retained solely by USON; neither affiliated practices nor their physicians received any of these fees. In addition, any costs incurred in connection with providing these services were borne solely by USON. As a result, these educational, marketing and communication services were operated separate from purchasing and clinical research relationships. Affiliated physicians did not participate in either the revenues or costs associated with these services. Therefore, the revenues and costs were excluded from the analysis performed by USON for the GAO.

(A combined response is offered for the next two inquiries)

Specify the total dollar amount of any grants or sponsorship of USON activities that USON (or any of its corporate predecessors, including but not limited to Texas Oncology[1] and American Oncology Resources) received at any time, since January 1, 1997, to the present from any pharmaceutical manufacturing company.

For each grant or sponsorship included in Request No. 1, provide the date of the grant, the amount of the grant, the alleged purpose of the grant, the activities on which the grant funds were actually expended, and whether the grant was agreed to as part of an overall drug purchasing contract.

As noted earlier, USON maintains two principal relationships with pharmaceutical manufacturing companies, each of which are operated separately from purchasing and clinical research relationships. First, USON provides comprehensive FDA-audited services to practices engaged in clinical cancer research with pharmaceutical companies. Second, USON provides educational, research and marketing services in the oncology community. As part of these activities, USON organizes and facilitates communications, through both conferences and electronic media, among pharmaceutical companies, oncologists, oncology nurses and cancer patients.

[1]Please note that Texas Oncology P.A. is not a predecessor company to USON.

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Fees received by USON from pharmaceutical companies and other vendors for these services are retained by USON. Neither affiliated practices nor their physicians received any of these fees. In addition, any costs incurred in connection with providing these services are borne solely by USON. Therefore, educational, marketing and research service revenues were excluded from the analysis performed by USON for the GAO.

The estimated total revenues provided (from 1997 to 2000) by pharmaceutical manufacturing companies in connection with educational, marketing and research services, and related expenses, are provided below:

Year	Sponsorship / Grant Revenues (Estimated)	Related Expenses (Estimated)	Net Revenues (Estimated)
2000	$11,220,000	$7,941,432	$3,278,568
1999	$6,862,000	*	*
1998	$1,998,500	*	*
1997	*	*	*

* Above amounts represent the information we have been able to compile as of the date of this letter. Work continues to identify all relevant sponsorship / grant revenues and related expenses. Please also note that the figures provided for 1998 and the first half of 1999 reflect the figures prior to the merger of AOR and PRN.

State whether USON (or any of its corporate predecessors, including but not limited to Texas Oncology and American Oncology Resources) has ever had any contractual arrangements with any pharmaceutical manufacturing company for the purchase of pharmaceuticals that also required or included as a provision of the contract the provision of any grants or sponsorship of any kind by the pharmaceutical company to USON or any of its corporate predecessors. If so, please provide a copy of each such contract.

It is USON's policy that pharmaceutical purchasing contracts do not require or include any provisions regarding grants or sponsorship, and no current pharmaceutical purchasing contract requires or includes grants or sponsorship. We are aware of one pharmaceutical purchasing contract, which was entered into by a corporate predecessor and terminated in 1999, that included a provision regarding sponsorship services. The sponsorship fees (totaling $250,000 for the twelve-month term, which was included in the 1998-1999 revenues in the table provided in response to the previous question) corresponded to the value of those services provided and were entirely unrelated to and were not conditioned upon the purchase of any pharmaceuticals.

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In conclusion, Mr. Chairman, I want to assure you that we have made, and will continue to make, every effort to support the reform of Medicare's flawed system for reimbursing drugs and medical services. Reflecting upon the experiences of our affiliated physicians and nurses, I can offer that the Committee's initiative, though difficult, will be of tremendous value to assuring that patients with cancer will continue to enjoy access to the high quality, cost-effective, community-based care they need. I hope that this letter will assist you in this effort.

As always, USON remains committed to assisting the Subcommittee in its efforts to reform the Medicare program's reimbursement of oncology drugs and practice expenses. Please do not hesitate to contact me if additional information is needed.

Sincerely,

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Leo E. Sands
Executive Vice President
Chief Compliance Officer

Attachments

cc: The Honorable W.J. "Billy" Tauzin, Chairman
The Honorable John D. Dingell, Ranking Member
The Honorable Peter Deutsch, Ranking Member
Subcommittee on Oversight and Investigations

US Oncology, Inc.
R. Dale Ross, Chief Executive Officer
Phillip H. Watts, Esq., General Counsel
Eric Berger, Vice President, Planning and Public Policy

Jenkens & Gilchrist, A Professional Corporation
Susan B. Murphy, Esq.
Iden Grant Martyn, Esq.
Robert W. Liles, Esq.

Ernst & Young, LLP
Carole Faig

DC 110886 v 1, 22869.00139

Jenkens & Gilchrist
A PROFESSIONAL CORPORATION

1100 LOUISIANA
SUITE 1800
HOUSTON, TEXAS 77002

(713) 951-3300
FACSIMILE (713) 951-3314

www.jenkens.com

AUSTIN, TEXAS (512) 499-3800
CHICAGO, ILLINOIS (312) 425-3900
DALLAS, TEXAS (214) 855-4500
LOS ANGELES, CALIFORNIA (310) 820-8800
NEW YORK, NEW YORK (212) 704-6000
SAN ANTONIO, TEXAS (210) 246-5000
WASHINGTON, D.C. (202) 326-1500

Susan B. Murphy
(713) 951-3362
smurphy@jenkens.com

September 10, 2001

SENT BY FAX TO: (202) 225-1919

Mark Paoletta
Chief Counsel
Subcommittee on Oversight and Investigations
House Energy and Commerce Committee
Rayburn House Office Building
Room 2125
Washington, DC

Re: Request for Information Related to Proposal Prepared by Pharmacia & Upjohn

Dear Mr. Paoletta:

Thank you for your willingness to work with our client, US Oncology, Inc. (USON), as part of the House Energy and Commerce Committee's efforts to reform the Medicare program's reimbursement of oncology drugs and practice expenses.

It is our understanding that you have questions related to a proposal that was prepared in 1997 by Pharmacia & Upjohn. Our client placed a call to your office earlier today in an effort to schedule a meeting with you tomorrow, prior to Wednesday's hearing. Since we have not heard back, we would like to proceed and address your questions as best we can at this time.

At the outset, please note that our initial review indicates that this document was not executed by our client. Moreover, it is important to note that USON did not prepare the document in question. As a result, USON is not in a position to speak to the motives or intentions of the preparers. Nevertheless, to the extent possible, we can provide a general discussion of how grant funds are used in the educational setting.

USON uses educational funding provided by pharmaceutical companies to present accredited Continuing Medical Education (CME) for USON affiliated practices. USON contracts with an independent third-party which maintains complete direction over the curriculum and content of the programs. Pharmaceutical companies are required to relinquish all control over how the training is presented and the information provided is unbiased and meets all requirements for certification. In

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this manner, affiliated physicians, nurses and other medical professionals are able to receive the education necessary to deliver the highest quality patient care and treatment.

As always, USON remains committed to assisting the Committee in its efforts to reform the Medicare program's reimbursement of oncology drugs and practice expenses. Please do not hesitate to contact me if additional information is needed.

Very truly yours,

Susan Murphy
by: RB
Susan B. Murphy

cc: David Marventano
Chief of Staff
House Energy and Commerce Committee

Patrick Morrisey
Deputy Chief of Staff
House Energy and Commerce Committee

CHUCK CLAPTON

ONE HUNDRED SEVENTH CONGRESS

U.S. House of Representatives

Committee on Energy and Commerce

Washington, DC 20515–6115

W.J. "BILLY" TAUZIN, LOUISIANA,
CHAIRMAN

September 14, 2001

R. Dale Ross
Chief Executive Officer & Chairman
US Oncology
16825 Northchase Dr.
Suite 1300
Houston, Texas 77060

Dear Mr. Ross:

As you know, the Committee on Energy and Commerce is reviewing the Medicare drug reimbursement system, and has had several communications with U.S. Oncology (USON) regarding the issue of inflated drug reimbursements, as well as your contention that these profits on drugs are necessary to cover other expenses of your member practices for which Medicare allegedly does not provide full reimbursement.

I am aware that, in connection with the ongoing Congressional inquiries, USON hired the accounting firm Ernst & Young to conduct an audit of USON reimbursements and expenditures for Medicare-covered drugs, as well as other related practice expenses and reimbursements. The results of this audit would appear to indicate that USON received roughly $92 million in excessive Medicare drug reimbursements, while receiving under-reimbursement from Medicare for practice expenses totaling roughly $83 million.

Committee staff have reviewed the report and have questions about whether the audit's calculations of USON's drug expenditures are truly reflective of the costs USON incur in purchasing drugs, thus possibly inflating the total costs and decreasing the margin of profit it receives from Medicare. For example, the Committee has obtained documentation indicating that USON and/or its predecessors received rebates and free goods from pharmaceutical companies as part of its drug purchasing arrangements. The Committee also has documentation reflecting that USON and/or its predecessors also received significant grants from pharmaceutical companies for various purposes and uses. Yet we are not certain whether Ernst & Young included these other payments or in-kind contributions from the drug companies when calculating USON's true cost of purchasing pharmaceuticals.

Because two calls to your outside counsel to discuss this matter have not been returned, and because we have re-noticed a hearing on Medicare drug reimbursements for next Friday, September 21, 2001, I am writing to you today to request information about USON's true cost of purchasing drugs and your contractual relationships with pharmaceutical companies. Specifically, I am requesting that, pursuant to Rules X and XI of the U.S. House of Representatives, USON provide to the Committee the following information by Wednesday, September 19, 2001:

1. Specify the total dollar amount of any grants or sponsorship of USON activities that USON (or any of its corporate predecessors, including but not limited to Texas Oncology and America Oncology Resources) received at any time since January 1, 1997 to the present from any pharmaceutical manufacturing company.

2. For each grant or sponsorship included in response to Request No. 1, provide the date of the grant, the amount of the grant, the alleged purpose of the grant, the activities on which the grant funds were actually expended, and whether the grant was agreed upon as part of an overall drug purchasing contract.

3. State whether USON (or any of its corporate predecessors, including but not limited to Texas Oncology and America Oncology Resources) has ever had any contractual arrangement with any pharmaceutical manufacturing company for the purchase of pharmaceuticals that also required or included as a provision of the contract the provision of any grants or sponsorships of any kind by the pharmaceutical company to USON or any of its corporate predecessors. If so, please provide a copy of each such contract.

4. Describe the methodology employed by Ernst & Young in calculating the cost of pharmaceutical purchases by USON, including whether the auditors accounted for such grants, sponsorships, rebates, free goods or other off-invoice discounts in determining such costs.

If you have any questions about the above request, please contact Mr. Mark Paoletta, Committee Chief Counsel for Oversight and Investigations, at (202) 225-2927. Thank you for your prompt reply to these requests.

Sincerely,

James Greenwood, Chairman
Subcommittee on Oversight and
Investigations

cc: The Honorable W.J. "Billy" Tauzin, Chairman
The Honorable John D. Dingell, Ranking Member
The Honorable Peter Deutsch, Ranking Member
Subcommittee on Oversight and Investigations

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Q			**SPREADS CONTRIBUTE TO OVERUTILIZATION, HAVE PUBLIC HEALTH CONSEQUENCES**
	1	12-13-1999	HHS OIG Report
R			**SPREADS CONTRIBUTE TO OVERUTILIZATION, HAVE PUBLIC HEALTH CONSEQUENCES**
	1		Etopophos: Executive Summary
	2		Hospital Pharmacist Report on *S. aureus* with diminished susceptibility to vancomycin
	3		1995 Red Book: Vancomycin Hydrochloride
	4		Florida Infusion 1995 Catalog: Vancomycin
	5		1996 Red Book: Vancomycin Hydrochloride
	6		Florida Infusion 1996 Catalog: Vancomycin
	7		2000 Red Book: Vancomycin Hydrochloride
	8		McKesson Econolink System, Facility: Ven-a-Care Vancomycin Hydrochloride
S			**EFFECT OF AWP SPREAD ON MEDICAID**

			(LOUISIANA)
	1		Examples of Excessive Reimbursements for Pharmaceuticals by Louisiana Medicaid Pharmacy Program
	2		State-to-State Price comparison of Bristol-Myers Cefadroxil
	3	02-07-2001	WSJ Article: "Facing an Impending Budget Crunch, States Seek to Curb Medicaid Costs"
T			**HCFA DID NOTHING DESPITE BEING AWARE OF PROBLEM**
	1	06-12-1997	Ven-a-Care Letter to Dr. Bruce Vladeck (HCFA Administrator), re: HCFA's Knowing Squandering of More than One Billion Dollars of Medicare Funds for Parenteral Nutrition
	2	08-13-1997	Ven-a-Care Letter to Dr. Bruce Vladeck (HCFA Administrator), re: HCFA's knowing Squandering of Tens of Millions of Dollars Annually in Precious Medicare and Medicaid Program Funds by not stopping Carriers and Agencies from paying Providers too much
	3	06-01-1998	Ven-a-Care Letter to Ms. Nancy-Ann Min DeParle (HCFA Administrator), re: HCFA's Proposed Methodology Revision for Payment of Drugs and Biologicals
U			**TEXAS HAS BEEN THE MOST AGGRESSIVE STATE IN ATTEMPTING TO ENSURE ACCURATE RREPORTING OF PRICES**
	1	04-20-1994	SmithKline Beecham: Letter to Martha McNeill of Texas Department of Health
	2	05-16-1994	Letter from McNeil to Gershon of SmithKline Beecham
	3		Florida Infusion Prices for Kytril
	4		Texas Anzemet Application
	5		Prices for Anzemet from Oncology Therapeutics Network
V			**QUESTION ADDRESSING THE CONSERVATIVE NATURE OF THE GAO ESTIMATES OF PROFITS FROM THESE DRUGS**

IMMUNEX

January 12, 1995 VIA FAX

Roni Lane
Red Book
5 Paragon Drive
Montvale, NJ 07645

Dear Roni:

Below you will find a list of new suggested Average Wholesale Prices (AWPs) for selected Immunex products, along with a new NDC fo[redacted]all effective January 10, 1995.

Also, please note that the following product will no longer be sold in single vials and will be available only in boxes of ten. Its AWP has been multiplied by ten and is in the table below. Each vial size has a new NDC and is now available under Immunex packaging. These changes are effective January 10, 1995.

Product	Old NDC	New NDC	New Suggested AWP
Leucovorin Calcium for Injection, preservative-free, cryodesiccated powder			
box of 10 vials			
50 mg	00205-5330-92	58406-0621-37	$215.30
100 mg	00205-4646-94	58406-0622-35	$394.10
350 mg	00205-4645-77	58406-0623-33	$1379.40

Please update your databases accordingly. A new copy of Immunex's Average Wholesale Price Product Pricing Guide will be sent to you next week. If you have any questions, call me at (206) 389-4320. Thank you.

Sincerely,

Mary Lipinsky
Manager, Health Care Policy

A-1

IMMUNEX

May 24, 1991

Beth Rader, Data Acquisition Coordinator
First Data Bank
11 Bayhill Drive
Suite 350
San Bruno, CA 94066

Dear Beth:

In a conversation with your colleague Larry yesterday, I learned that First Data Bank currently shows the correct direct prices for LEUKINE™, but that the AWP prices are not correct. I am therefore requesting that you revise the AWP prices immediately, so that your customers have correct information against which to process claims. The pricing data for LEUKINE™ follows:

NDC NUMBER	VIAL SIZE	DIRECT PRICE	AWP
58406-002-01	250 mcg	$85.00	$106.00
58406-001-01	500 mcg	$160.00	$200.00

Larry indicated that the correction could be made as soon as you received this written notification, so I am Federal Expressing it to you. Would you please let me know when the corrections are on your system, and when your customers will have the correct information? My number at Immunex is (206) 587-0430, Ext. 796.

FDB 001129

A-2

A-3

Christopher Cheney

Bayer

08/07/97 01:15 PM

Pharmaceutical Division

To: Brian Shortell/WESTH/PH/US/BAYER
cc:
Subject: Re: Recombinate AWP Change

FYI ... It looks like if the reports are true we will need to follow suit.

---------- Forwarded by Christopher Cheney/BAYER-US-NOTES on 08/07/97 01:13 PM ----------

David Mahoney
08/07/97 12:19 PM

To: Christopher Cheney/BAYER-US-NOTES
cc:
Subject: Re: Recombinate AWP Change

Chris, if Baxter has increased their AWP then we must do the same. Many of the Homecare companies are paid based on a discount from AWP. If we are lowed than Baxter then the return will be lower to the HHC. It is a very simple process to increase our AWP, and can be done overnight. Lets talk about this next week at our meeting in Old Saybrook.
08/06/97 06:35 AM

Christopher Cheney

Bayer

08/06/97 06:35 AM

Pharmaceutical Division

To: Brian Shortell/WESTH/PH/US/BAYER
cc: Carole Guthrie/WESTH/PH/US/BAYER, David Mahoney/BAYER-US-NOTES, Terry Tenbrunsel/BAYER-US-NOTES
Subject: Recombinate AWP Change

Carole reports that a rep has heard that Baxter recently increased the AWP for Recombinate from $1.18 to $1.24. Do we have any means for verifying this information? Secondly if the info is correct would it be possible for us to match their increase? Would you be able to comment on the pro's and con's of a change to our AWP?

Call me when you get a chance.

B-2 Copy to Jane

Glaxo Memo

B-1

To: *Jim Dawson*
Andy Harrisfield
Patti Pozella
Rick Sluder
From: *Nancy Pekarek*
Date: *10/25/94*
Subject: *Issue considerations on Zofran pricing strategies*

Attached is a draft outlining the issues we discussed yesterday regarding Zofran pricing strategies. Please review for further discussion this afternoon.

Zofran pricing recommendation considerations

If Glaxo chooses to increase the NWP and AWP for Zofran in order to increase the amount of Medicaid reimbursement for clinical oncology practices, we must prepare for the potential of a negative reaction from a number of quarters. Some likely responses:

1) Press: Glaxo's health care reform messages stressed the importance of allowing the marketplace to moderate prices. On the surface, it seems that in response to the entrance of a competitor in the market, Glaxo has actually raised its price on Zofran -- perhaps twice in one year. How do we explain that price increase on a drug that is already been cited in the press as one of, if not the most expensive drug on the hospital formulary?

   If we choose to explain the price increase by explaining the pricing strategy, which we have not done before, then we risk further charges that we are cost shifting to government in an attempt to retain market share.

2) Congress: Congress has paid a good deal of attention to pharmaceutical industry pricing practices and is likely to continue doing so in the next session. How do we explain to Congress an 8% increase in the NWP between January and November of 1994, if this policy is implemented this year? How do we explain a single 9% increase in the AWP? What arguments can we make to explain to congressional watchdogs that we are cost-shifting at the expense of government? How will this new pricing structure compare with costs in other countries?

3) Private insurers, out-of-pocket payers: These groups, and perhaps others, are likely to incur greater costs as a result of this pricing strategy.. How will they be affected? What response do we have for them?

Other questions to consider:

1. What percentage of our Zofran business in the clinical setting is subject to Medicaid reimbursements? If this proportion of the business is relatively small, why implement such a sweeping policy? Have we considered and tried other options for retaining market share short of a pricing strategy that will be seen as an exhorbitant increase?

2. Both before and after the entrance of Kytril on the market, Glaxo's public position has been that the company would not compete on the basis of price, but rather continue to reinforce the message that Zofran provides therapeutic value in the marketplace. If we do try to explain the pricing rationale, we seem to be doing an about face. What does this say about the stability of our product, and the future of a company that has taken the public position that our future depends on the strength of newer products like Zofran?

3. How will SKB respond to Glaxo's new pricing policy? Are we igniting a price war? If SKB lowers their price again, how do we respond?

4. What kind of response can we expect from consumer advocates? How does Glaxo respond to those advocates?

5. How do we respond to critics' charges that this policy proves that the pharmaceutical companies are unfairly discriminating against independent pharmacists by offering discounts to different classes of trade as well as other issues in that debate?

6. Do we have plans to use this same strategy with regard to other Glaxo products?

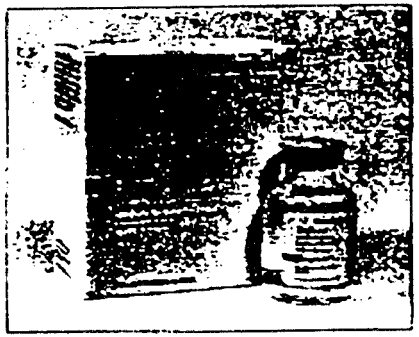
7. Does this pricing policy, and similar policies implemented by other companies, provide evidence to reform advocates who support the establishment of government price review boards? Is the industry helping to moderate health care costs when it implements policies that increase the cost of pharmaceuticals to government?

1-800-624-0152

FLORIDA INFUSION CHEMONET

FEBRUARY 1995

ZOFRAN: Higher AWP...higher reimbursement



Effective January 3, 1995, Glaxo has increased the acquisition costs of Zofran injection. The new AWP is set at $233.02. However, the company has provided incentives to the market place which will ensure that the Zofran price to physicians and clinics will be lower than the contractual price available prior to the increase. Effective January 10, 1995 the price of Zofran has been reduced by most distributors to $161.00. We expect this price to be available for the next three or four weeks and we don't expect that the price will afterwards increase considerably.

B-2

B-3

HEALTHIQ

750 THE CITY DRIVE, SUITE 210
ORANGE, CA 92668-4940
TELEPHONE 714.750.4474
800.866.4474
FACSIMILE 714.750.5513
INTERNET INFO@HEALTHIQ.COM

March 15, 1996

Bob Boata
Kytril Special Projects
SmithKline Beecham Pharmaceuticals
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Bob:

Thank you for sending the information regarding Glaxo's new pricing strategy. I understand your intent was for HEALTHIQ to follow up our recent, and highly effective, correspondence to the Medicare Part B Medical Directors with an update regarding Glaxo's latest attempt to "gouge" the Medicare system. However, we believe this would not be in SmithKline Beecham's best interest, for the following reasons:

1. Medicare guidelines under the Part B benefit stipulate that reimbursement for pharmaceuticals will be based on the lower of the actual charge, the average wholesale prices (AWP) for the generic form of the drug, or in the case of multiple source drugs, the median of all the generic AWPs or an estimate of actual acquisition costs. Although HCFA has not implemented a system to monitor actual acquisition costs, and currently "defers" to AWP, there have been, and continue to be, serious discussions regarding this matter.

2. A recent report released by the Department of Health and Human Services Office of the Inspector General, which focused specifically on Medicare payment methodologies for three prescription drugs used by nebulizer patients, concluded that significant cost savings to the Medicare program would result from implementing new reimbursement methodologies, for example, drug rebate programs, discounts off AWP, or "inherent reasonableness" – basing payment of drugs on the estimated acquisition cost.

3. In speaking with Dr. David P. Sheridan, Medical Director for South Carolina, he indicated Medicare had no intention of paying more than cost. As a result, this carrier will require attachment of an invoice with every claim submitted for Zofran pre-filled bag. HEALTHIQ will continue to follow-up with other Medical Directors to determine their policy regarding this issue, and provide SmithKline Beecham with a summary of our findings.

4. From the communications received to date, the letter submitted by Physician Homecare Associates, Inc., ostensibly written on behalf of physicians and other healthcare providers, appeared to be greatly appreciated by the Medical Directors. A follow-up letter apprising Medicare of an increase in Glaxo's AWP and a preferred discount to purchasers (which would seem to benefit providers), might appear "peculiar" and prompt questions as to the "true" identity of Physician Homecare Associates.

As a result of the issues raised above, HEALTHIQ is concerned that highlighting the difference between the actual acquisition cost and the published AWP may not only increase attention to Glaxo's pricing practices, but may provide the impetus for HCFA to implement a system that could impact not only reimbursement of anti-emetics, but all pharmaceutical and biological products. The ramifications could extend well past Medicare to include Medicaid programs (also administered by HCFA) as well as private payors (who tend to mimic policies and procedures implemented by public payors).

Therefore, HEALTHIQ feels it would be best not to pursue this matter with the Medicare Part B Medical Directors.

Bob, please let me know your thoughts.

Best regards,

Jesus E. Alvarado
Senior Vice President

B-4

02/28/94 Vick F-1495 rz 940310.003

AWP and WAC Prices

Price Strategy

- Prices are low enough to claim "bragging rights" without initiating a market-destabilizing price war
- AWP is high enough to provide an attractive reimbursement margin for customers
- Moderate list price advantage disguises true customer acquisition cost advantage

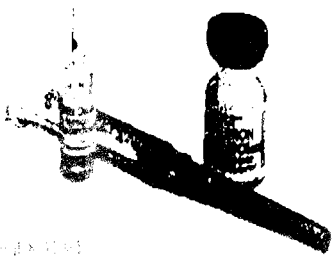
1-800-624-0152

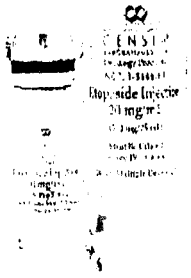
FLORIDA INFUSION CHEMONET

AUGUST 1994

LUPRON DEPOT

$372.00 6 Kits or more





ETOPOSIDE

Gensia's Etoposide injection is a cost saving generic equivalent to Bristol Myers' VePesid.

100mg MDV

85.00

500mg MDV

415.00

C-1

C-2

1-800-624-0152

FLORIDAINFUSION

PHARMACY ONLY

10-09-95 TO 10-13-95

ETOPOSIDE

$49.00

100mg $295.00

500mg $580.00

1gram .....

1-800-624-0152

FLORIDAINFUSION

WEEKLY SPECIALS
02-26-96 TO 03-01-96

THINGS ARE WARMING UP IN FLORIDA WITH THE HOTTEST SALE OF THE SEASON...

ETOPOSIDE

C-3

Buy 10 at our already reduced price and

GET ONE FREE

HUGE SAVINGS

	REGULAR LOW PRICE	AFTER FREE GOODS
100mg	$36.00	$32.73
500mg	$220.00	$200.00
1gram	$420.00	$381.00

1-800-624-0152

FLORIDA INFUSION CHEMONET

JANUARY 1997

HAPPY NEW YEAR!!!

ETOPOSIDE

100mg	$14.00
500mg	$70.00
1000mg	$140.00

C-4

Medicare & Medicaid Continue to Pay Based on $141.97 Despite True Price Decline of 93.8%

Company	Drug	NDC	Date	AWP	Relator Cost
Gensia	Etoposide	00703-5643-01	8/94	$141.97	$85.00
Gensia	Etoposide	00703-5643-01	4/95	$141.97	$67.62
Gensia	Etoposide	00703-5643-01	10/95	$141.97	$49.00
Gensia	Etoposide	00703-5643-01	2/96	$141.97	$36.00
Gensia	Etoposide	00703-5643-01	9/96	$141.97	$18.00
Gensia	Etoposide	00703-5643-01	1/97	$141.97	$14.00

C-5

ABBOTT
Alternate Site
Product Sales

D-1

High Tech Products for Alternate Site and Home Health Care

March 10, 1994

Mr. Rudy Ciccarello
Florida Infusion
1053 Progress Court
Palm Harbor, FL 34683

Dear Rudy:

I have recently accepted the position of Manager, Distributor Relations. Jeff Hamlin has accepted a position as one of our hospital based district managers in Raleigh, North Carolina. As part of the transition I found that we had not yet notified you of some price/product adjustments that were recently made to your agreement with us.

The first three pages, identified as *Florida Infusion Price Changes* indicate the products in which prices were changed and their new contract price. Favorable factory costs in 1994 have lead the way for these price reductions! These products have been included in the comprehensive price list that has also been enclosed. These changes were effective February 25, 1994, we apologize for the delay in communicating this information to you.

I look forward to meeting with you in the near future, before then, if there are any questions or concerns that I can assist you with, please do not hesitate to call (708) 937-5916.

Sincerely,

Clifford J. Krajewski
National Account Manager

D-2

ALTERNATE
CONTRACT MARK

May 26, 1994

TO: Field Sales Force
District Managers

CC: Cindy Dawson
Mike Dorr
Phil Elliott
Cliff Krajewski
Karla Kreklow
Debbie Longley
Mary Beth Manso
Chris Snead
Dennis Walker

RE: Current Red Book AWP's

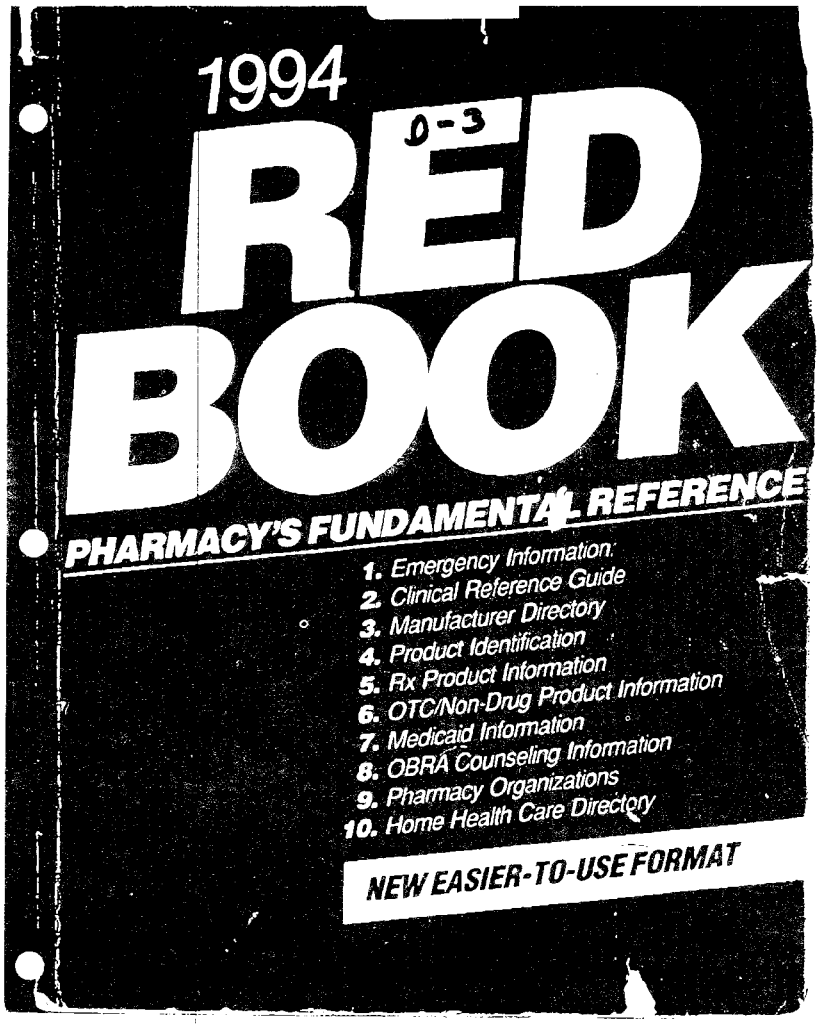
As you are aware, on at the beginning of April, Abbott took a list price increase. This also has an effect on our AWP (Average Wholesale Price) which Red Book quotes for reimbursement purposes. Therefore, Mike Heggie was able to get Red Book to send a listing of the "new" AWP's for ALL of our products, which will be effective through next April. I hope this information is helpful and if you have any questions, please feel free to contact me.

Best regards.

Steve Kipperman

ABT006333

Confidential
AB0019135


1994
D-3
RED
BOOK
PHARMACY'S FUNDAMENTAL REFERENCE
1. Emergency Information
2. Clinical Reference Guide
3. Manufacturer Directory
4. Product Identification
5. Rx Product Information
6. OTC/Non-Drug Product Information
7. Medicaid Information
8. OBRA Counseling Information
9. Pharmacy Organizations
10. Home Health Care Directory
NEW EASIER-TO-USE FORMAT

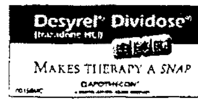
KEY TO LISTINGS

AWP: Average Wholesale Price
NDC: National Drug Code
PROD/MFR:
  PRODUCT (Bold, upper case)
  MANUFACTURER (Bold, upper/lower case)
SRP: Suggested Retail Price (if available)
DP: Direct Price (if available)
OBC: Orange Book Code (Drug Equivalence)

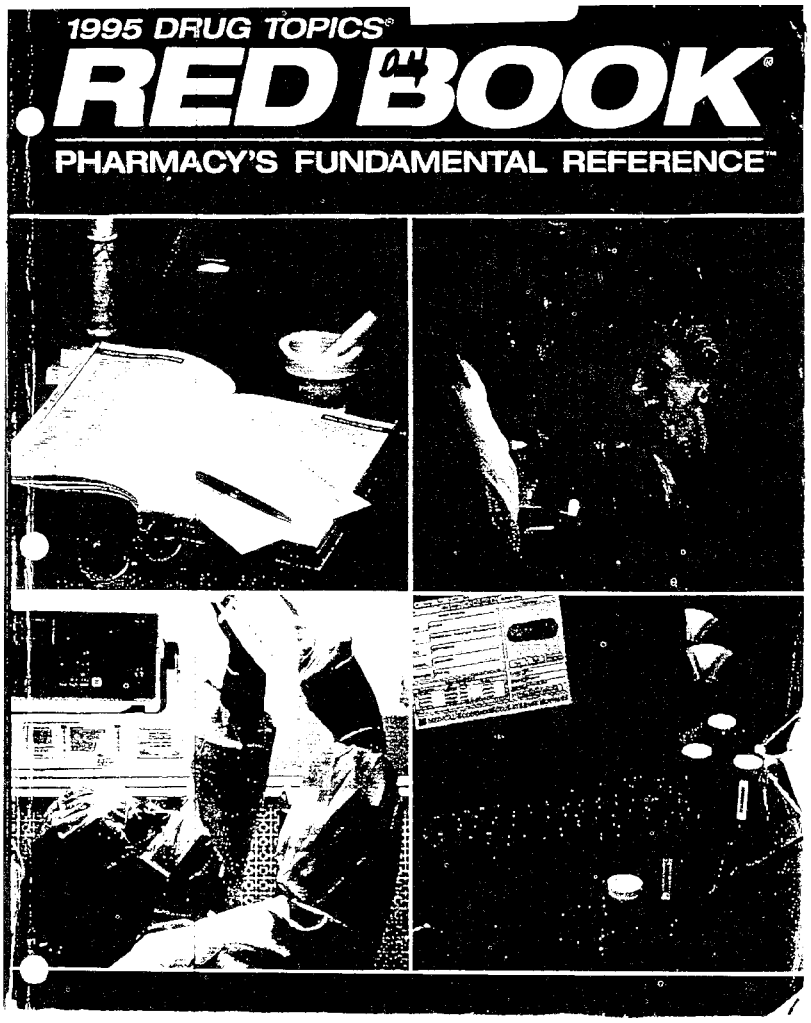
PROD/MFR	NDC	AWP	DP	OBC
(Allgen)				
CAP, (YLW SOFT GEL CAPS)				
250 mg, 100s ea	00405-5014-01	28.45		AB
SYR, (CHERRY MINT)				
200 mg				
440 ml	00405-3898-18	30.90		AA
(Chase Lab.)				
CAP, 250 mg, 100s ea	64429-3184-01	22.00		AB
(Copley)				
SEE SECTION 3 FOR MFR CATALOG				
SYR, (RED, CHERRY-MINT)				
250 mg/5 ml				
16 oz	23736-0832-07	46.30		EE
(Geneica)				
CAP, 250 mg, 100s ea	00302-7679-01	24.10		EE
(Geneva Pharm)				
CAP, 250 mg, 100s ea	00781-2203-01	18.75		AB
SYR, 250 mg/5 ml				
480 ml	00781-8701-18	41.50		AA
(Goldline)				
CAP, (SOFTGEL, OBLONG-ORANGE)				
250 mg, 100s ea	00182-1784-01	44.90		AB
SYR, 250 mg/5 ml,				
480 ml	00182-6115-40	48.25		AA
(International Lab)				
CAP, 250 mg, 100s ea	00905-4120-00	47.50		AB
(Interstate)				
CAP, 250 mg, 100s ea	00814-8740-14	27.00		EE
(Major)				
CAP, 250 mg, 100s ea	00904-2101-60	47.10		AB
100s ea	00904-7788-60	47.10		AB
250 mg/5 ml,				
16 oz	00904-2183-16	41.95		AA
(Martec)				
CAP, 250 mg, 100s ea	52555-0325-01	44.44		AB
(Mason Distrib.)				
CAP, 250 mg, 100s ea	11845-0185-01	44.82		AB
(Moore, H.L.)				
CAP, (SOFT GEL)				
250 mg, 100s ea	00839-7180-06	40.49	29.99	AB
(SOFTGEL)				
250 mg, 100s ea	00839-7840-06	40.49	29.99	
SYR, 250 mg/5 ml,				
480 ml	00839-7194-69	40.64	30.25	AB
(Parmed)				
CAP, 250 mg, 100s ea	00349-8735-01	37.50		AB
(Pennex Pharm)				
SYR, 250 mg/5 ml,				
150 ml	00426-8821-36	34.00		AA
480 ml	00426-8821-16	55.00		AA
(Pharmaceutical Basic)				
CAP, 250 mg, 100s ea	00132-1907-02	32.00		AB
(Professional Pharm)				
TAB, 250 mg, 30s ea	10488-4477-28	5.02		AB
(Purepac)				
CAP, 250 mg, 100s ea	00228-2455-10	33.58		AB
(Qualitest)				
CAP, 250 mg, 100s ea	00603-4234-21	28.75		AB
SYR, 250 mg				
480 ml	00603-1846-58	45.65		AA
(Rawar)				
SYR, 250 mg/5 ml,				
480 ml	00186-0821-16	13.95		EE
(Rugby)				
CAP, (SOFT GEL)				
50 mg, 100s ea	00536-4477-01	23.05		AB
SYR, 250 mg/5 ml,				
480 ml	00536-2390-85	32.47		AA

PROD/MFR	NDC	AWP	DP	OBC
(Schein)				
CAP, 250 mg, 100s ea	00364-0822-01	24.50		AB
SYR, 250 mg/5 ml				
480 ml	00364-2133-16	37.27		AA
(U S Trading)				
CAP, (10X10)				
250 mg,				
100s ea UD	56126-0106-11	14.40		AB
(UDL)				
CAP, (10 X 10 U S P)				
250 mg,				
100s ea UD	51079-0283-20	26.13	22.65	AB
(United Research)				
CAP, 250 mg, 100s ea	00677-1078-01	25.00		AB
SYR, (RED/CHERRY FLAVOR)				
250 mg/5 ml,				
480 ml	00677-1195-33	42.62		EE
(Xactdose)				
SYR, (U S P)				
250 mg/5 ml,				
5 ml, 100s ea UD	50962-0024-05	75.60	52.22	EE
VALRELEASE, C-IV (Roche)				
diazepam				
CA, (RX PAK)				
15 mg, 30s ea	00004-0143-54	48.77		EE
(S.R.)				
15 mg, 100s ea	00004-0140-01	161.85		EE
VARACET, C-III (GM Pharm)				
hydrocodone w/apap				
TAB, 5 mg-500 mg,				
100s ea	58809-0834-01	24.95		EE
VANADOM (GM Pharm)				
carisoprodol				
TAB, 350 mg, 100s ea	76488-0424-01	111.96		EE
VANCENASE AQ (Schering)				
beclomethasone dipropionate				
ARC, (NASAL SPRAY)				
25 gm	00085-0238-02	31.01		BN
VANCENASE POCKETHALER (Schering)				
beclomethasone dipropionate				
ARC, (NASAL INHALER)				
0.042 mg/inh				
7 gm	00085-0540-02	28.72		BN
VANCERIL (Schering)				
beclomethasone dipropionate				
ARC, (INHALER)				
16.8 gm	00085-0736-04	28.72		BN
VANCOCIN HCL (Lilly)				
vancomycin				
CAP, (I.D.)				
125 mg, 20s ea	00002-3125-42	94.50		EE
250 mg, 20s ea	00002-3126-42	185.01		EE
INJ, 500 mg/100 ml				
100 ml, 12s ea	00002-7497-12	132.05		
PDI, 500 mg, ea	00002-1444-01	7.80		AP
(TRAY PACK MULTI)				
500 mg, 10s ea	00002-1444-10	78.00		AP
(ADD-VANTAGE)				
500 mg, 10s ea	00002-7297-10	82.80		AP
1 gm, 10s ea	00002-7298-10	150.61		AP
10s ea	00002-7321-10	158.01		AP
(VIAL)				
10 gm, ea	00002-7386-01	158.01		AP
SOL, (POWDER FOR ORAL SOL)				
500 mg/6 ml,				
120 ml	00002-2372-37	376.21		EE
1 gm, 20 ml, 6s ea	00002-5165-16	205.21		EE
VANCOLED (Lederle Std)				
vancomycin				
PDI, 500 mg, 10s ea	00205-3154-05	55.84	48.05	AP
1 gm, 10s ea	00205-3164-15	111.70	92.12	AP
5 gm, ea	00205-3134-88	55.84	48.05	AP
(Abbott Hosp)				
PDI, (FLIPTOP VIAL-STERILE)				
500 mg, 10s ea	00074-4332-01	295.55		AP
(ADD-VANTAGE VIAL/STRILE)				
500 mg, 10s ea	00074-6534-01	105.57		
(FLIPTOP VIAL-STERILE)				
1 gm, 10s ea	00074-6533-01	688.88		AP
(ADD-VANTAGE VIAL/STRILE)				
1 gm, 10s ea	00074-6535-01	211.26		
(PHCY BULK PK-STERILE)				
5 gm, ea	00074-6509-01	132.02		AP
(Elkins-Sinn)				
PDI, 500 mg, 10s ea	00641-2778-43	188.12	150.50	AP
1,000 mg, 10s ea	00641-2779-43	375.62	300.50	AP

PROD/MFR	NDC	AWP	DP	OBC



PROD/MFR	NDC	AWP	DP	OBC
(Fujisawa) *See LYPHOCIN*				
(Lederle Std) *See VANCOLED*				
(Lilly) *See VANCOCIN HCL*				
(Schein)				
PDI, (10 ML)				
500 mg, 10s ea	00364-2472-43	70.00		AP
(30 ML)				
1 gm, 10s ea	00364-2473-51	140.41		AP
VANEX, C-III (Abana)				
guaifenesin				
EXP, 1 pt	12463-0129-16	34.53		
VANEX FORTE (Abana)				
com/phenylephrine/pyrilamine				
TAB, 100s ea	12463-0125-01	43.75		
VANEX-HD, C-III (Abana)				
chlorphenir/phenyleph/hydrocod				
LIC, 480 ml	12463-0530-16	21.37		
VANEX-LA (Abana)				
guaifenesin/phenylpropanolamin				
TTB, 75 mg-400 mg,				
100s ea	12463-0460-01	32.45		
VANILLA EXTRACT				
(Amend) *See VANILLIN*				
POW, (N F)				
125 gm	17137-0800-04	6.40		
VANOXIDE-HC (Dermik)				
benzoyl peroxide, hydrocortison				
LOT, 25 gm, 25 cc	00066-0424-25	21.35	17.83	
VANSIL (Pfizer)				
oxamniquine				
CAP, 250 mg, 24s ea	00069-6413-24	117.81	99.21	
VANTIN (Upjohn)				
cefpodoxime proxetil				
SUS, (GRANULES)				
50 mg/5 ml				
100 ml	00009-3531-01	28.38	23.65	
100 mg/5 ml,				
100 ml	00009-3615-01	54.00	45.00	
TAB, 100 mg, 20s ea	00009-3617-01	33.36	27.80	
100s ea	00009-3617-02	158.76	132.30	
100s ea UD	00009-3617-03	162.72	135.60	
200 mg, 10s ea	00009-3618-01	63.60	53.00	
100s ea	00009-3618-02	302.40	252.00	
100s ea UD	00009-3618-03	309.96	258.30	
VARICELLA ZOSTER IMMUNE GLOBULIN (Am.Red Cross)				
globulin, immune				
VIA, 125 u, 2.5 ml	14362-0118-02	75.00		
VASCOR (Mc Neil Pharm)				
bepridil hydrochloride				
TAB, (F.C. UNIT-OF-USE)				
200 mg, 30s ea	00045-0682-30	70.10		AB
(3X30 F.C.)				
200 mg, 90s ea	00045-0682-32	210.30		AB
(F.C.)				
200 mg				
100s ea UD	00045-0682-10	237.03		AB
(F.C. UNIT-OF-USE)				
300 mg, 30s ea	00045-0683-30	85.52		AB
(3X30 F.C.)				
300 mg, 90s ea	00045-0683-33	256.57		AB
(F.C.)				
300 mg,				
100s ea UD	00045-0683-10	313.56		AB
(F.C. UNIT-OF-USE)				
400 mg, 30s ea	00045-0684-30	94.45		AB
(3X30 F.C.)				
400 mg, 90s ea	00045-0684-33	265.35		AB
(F.C.)				
400 mg,				
100s ea UD	00045-0684-10	353.43		AB
VASCORAY (Mallinckrodt Medical)				
iothalamate (meg. & sod.)				
SOL, 50 ml	00019-0357-15	12.15		
100 ml	00019-0357-07	23.20		
200 ml	00019-0357-05	45.13		


1995 DRUG TOPICS®
RED BOOK®
PHARMACY'S FUNDAMENTAL REFERENCE™

PROD./MFR	NDC	AWP	DP	ORC
(URL)				
CAP, PO (SOFTGEL)				
250 mg, 100s ea	00677-1878-01	40.46		AA
SYR, PO (CHERRY)				
250 mg/5 ml,				
480 ml	00677-1156-33	42.88		EE
(Xanodyne)				
SYR, PO (10X10)				
250 mg/5 ml,				
5 ml 100s UD	10003-0215-54	75.40	64.22	EE
VALRELEASE (Roche Labs)				
diazepam				
CLR, PO (RX PAK)				
15 mg,				
30s ea, C-IV	00004-0148-54	51.88		
100s ea, C-IV	00004-0148-01	172.10		
VANACET (DM Pharm)				
apap/hydrocodone				
TAB, PO, 500 mg-5 mg,				
100s ea, C-III	58888-0853-0[illegible]	24.86		EE
VANADOM (Sal Pharm)				
carisoprodol				
TAB, PO, 350 mg, 100s ea	58891-0424-01	111.96		EE
VANADYL SULFATE (A-A Spectrum)				
POW, 100 gm	49452-8004-01	34.15	34.30	
1000 gm	49452-8004-02	209.55	188.60	
VANATRIP (GM Pharm)				
amitriptyline hydrochloride				
TAB, PO, 50 mg, 100s ea	58809-0717-01	59.08		AB
VANCENASE AQ (Schering)				
beclomethasone dipropionate				
SPR, NS, 0.042 mg/inh,				
25 gm	00085-0299-02	32.40		BX
(Southwood)				
[illegible]				
SPR, NS, 0.042 mg/inh,				
25 gm	58016-0234-01	38.71		BN
VANCENASE INHALER (Schering)				
beclomethasone dipropionate				
ARO, NS, 0.042 mg/inh,				
7 gm	00085-0041-03	30.01		BN
(Southwood)				
[illegible]				
ARO, NS, 0.042 mg/inh,				
17 gm	58016-6875-01	37.44		BX
VANCERIL (Key)				
beclomethasone dipropionate				
ARO, IH, 0.042 mg/inh,				
17 gm	00085-0736-04	30.01		BN
VANCOCIN HCL (Lilly)				
dextrose/vancomycin				
INJ, IJ (GALAXY SYSTEM)				
5%-500 mg/100 ml,				
100 ml 12s	00002-7461-12	132.05		
VANCOCIN HCL (Lilly)				
vancomycin hydrochloride				
PDI, IJ, 500 mg, ea	00002-1444-01	7.90		AP
(ADD-VANTAGE)				
500 mg, 10s ea	00002-7297-10	82.90		AP
(TRAY PACK)				
500 mg, 10s ea	00002-1444-10	79.00		AP
1 gm, 10s ea	00002-7321-10	158.01		AP
(ADD-VANTAGE)				
1 gm, 10s ea	00002-7288-10	160.81		AP
(BULK VIAL)				
10 gm, ea	00002-7305-01	156.01		AP
POR, PO, 250 mg/5 ml,				
20 ml ea	00002-6186-10	205.21		EE
500 mg/6 ml				
120 ml	00002-2372-47	278.21		EE
VANCOCIN HCL PULVULES (Lilly)				
vancomycin hydrochloride				
CAP, PO, 125 mg, 20s ea	00002-3125-42	64.50		EE
250 mg, 20s ea	00002-3126-42	190.01		EE
VANCOMYCIN				
SEE DEXTROSE/VANCOMYCIN				
VANCOMYCIN HYDROCHLORIDE (A-A Spectrum)				
POW, 1 gm,	49452-8096-02	74.75	87.30	
250 gm	49452-8096-01	24.50	22.06	
(Abbott Hosp)				
PD, IJ (ADD-VANTAGE)				
500 mg, 10s ea	00074-6534-01	108.78		
(FLIPTOP VIAL)				
500 mg, 10s ea	00074-4332-01	302.34		AP
(ADD-VANTAGE)				
1 gm, 10s ea	00074-6535-01	217.86		
(FLIPTOP VIAL)				
1 gm, 10s ea	00074-6533-01	604.44		AP
(BULK VIAL)				
5 gm, ea	00074-6480-01	135.80		AP
(Elkins-Sinn)				
PDI, IJ, 500 mg, 10s ea	00641-2770-42	188.13	150.50	AP
1 gm, 10s ea	00641-2779-43	375.63	300.50	AP
(Fujisawa) *See LYPHOCIN*				
(Lederle Std Prod)				
PDI, IJ, 500 mg, 10s ea	00205-3154-84	57.56	46.05	AP
1 gm, 10s ea	00205-3154-15	115.15	92.12	AP
5 gm, ea	00205-3154-06	57.56	46.05	AP
(Lilly) *See VANCOCIN HCL*				
(Lilly) *See VANCOCIN HCL PULVULES*				
(Schein)				
PDI, IJ, 500 mg, 10s ea	00364-2472-33	70.00		AP
1 gm, 10s ea	00364-2473-01	140.41		AP
VANEX EXPECTORANT (Abana)				
gg/hydrocodone/pseudoeph				
LIQ, PO				
100 mg-2.5 mg-30 mg/5 ml,				
480 ml, C-III	12463-0123-16	35.58		
VANEX FORTE (Abana)				
cpm/phenyleph/ppa/pyril				
TER, PO (CAPLETS)				
100s ea	12463-0125-01	51.24		
VANEX-HD (Abana)				
cpm/hydrocodone/phenyleph				
LIQ, PO, 2 mg-1.67 mg-5 mg/5 ml,				
480 ml, C-III	12463-0380-16	22.21		
VANEX-LA (Abana)				
gg/ppa				
TER, PO, 400 mg-75 mg,				
100s ea	12463-0400-01	33.42		
VANILLIN (A-A Spectrum)				
POW, 125 gm	49452-8100-01	10.40	8.48	
500 gm	49452-8100-02	29.80	24.80	
2500 gm	49452-8100-03	117.10	97.10	
(Amend)				
POW, (N.F.)				
120 gm	17127-0000-04	4.40		
(Lannett Oil)				
POW, (U.S.P.)				
30 gm	23036-4140-45	2.00		
120 gm	23036-4140-42	6.50		
480 gm	23036-4140-18	18.00		
VANOXIDE-HC (Dermik)				
benzoyl perox/hc				
LOT, TP, 5%-0.5%, 25 ml	00066-0424-25	22.21	18.51	
VANSIL (Pfizer Labs)				
oxamniquine				
CAP, PO, 250 mg, 24s ea	00069-3410-24	122.63	103.14	
VANTIN (Upjohn)				
cefpodoxime proxetil				
PDR, PO, 50 mg/5 ml,				
100 ml	00009-3531-01	26.38	23.85	
100 mg/5 ml,				
100 ml	00009-3615-01	54.00	45.00	
TAB, PO (UNIT OF USE)				
100 mg, 20s ea	00009-3617-01	34.89	28.91	
100s ea	00009-3617-02	165.11	137.59	
100s ea UD	00009-3617-03	166.22	141.02	
(UNIT OF USE)				
200 mg, 20s ea	00009-3618-01	66.14	55.12	
100s ea	00009-3618-02	314.50	262.08	
100s ea UD	00009-3618-03	327.36	285.83	
VARICELLA ZOSTER IMMUNE GLOBULIN (Amer Red Cross-Blood)				
globulin, immune				
INJ, IJ (VIAL)				
125 u, 2.5 ml	14362-0111-42	83.00		
VASCOR (McNeil Pharm)				
bepridil hydrochloride				
TAB, PO (UNIT OF USE)				
200 mg, 30s ea	00045-0682-34	73.10		AB
(3X30)				
200 mg, 90s ea	00045-0682-32	220.81		AB
100s ea UD	00045-0682-11	262.88		AB
(UNIT OF USE)				
300 mg, 30s ea	00045-0683-34	85.52		AB
(3X30)				
300 mg, 90s ea	00045-0683-32	259.15		AB
100s ea UD	00045-0683-11	328.92		AB
(UNIT OF USE)				
400 mg, 30s ea	00045-0684-34	94.45		AB
(3X30)				
400 mg, 90s ea	00045-0684-32	303.54		AB
100s ea UD	00045-0684-11	370.94		AB
VASERETIC 10-25 (Merck)				
enalapril/hctz				
SEE SECTION 4 FOR COLOR PHOTO				
TAB, PO, 10 mg-25 mg,				
100s ea	00006-0720-68	108.60	86.28	
(Allscripts)				
[illegible]				
TAB, PO, 10 mg-25 mg,				
30s ea	54569-3546-00	35.84		
VASOCIDIN (Ciba Ophth)				
predniso sod/sulfacet sod				
OIN, OP, 0.5%-10%,				
3.5 gm	00058-0046-01	11.58	9.65	AT
VASOCIDIN (Ciba Ophth)				
prednis sod phos/sulfacet sod				
GTT, OP, 0.25%-10%, 5 ml	00058-2887-05	12.50	11.25	AT
10 ml	00058-2887-10	18.06	15.05	AT
(Southwood)				
[illegible]				
GTT, OP, 0.25%-10%,				
10 ml	58016-6722-01	24.63		AT
VASOCON (Ciba Ophth)				
naphazoline hydrochloride				
GTT, OP, 0.1%, 15 ml	00058-2844-15	15.80	11.50	AT
VASOCON-A (Ciba Ophth)				
antazoline/naphazoline				
GTT, OP, 0.5%-0.05%,				
15 ml	00058-2088-15	13.32	11.10	AT
VASODILAN (Apothecon)				
isoxsuprine hydrochloride				
TAB, PO, 10 mg, 100s ea	00087-0643-01	28.82	25.14	
100s ea UD	00087-0643-06	34.98	31.73	
1000s ea	00087-0643-02	274.07	243.45	
20 mg, 100s ea	00087-0644-01	46.19	41.87	
1000s ea	00087-0644-06	408.47	373.27	
VASOPRESSIN (Amer Regent)				
INJ, IJ (M.D.V.)				
20 u/ml,				
0.5 ml 25s	00517-0610-25	75.00		
1 ml 25s	00517-1020-25	135.00		
(Fujisawa)				
INJ, IJ (M.D.V.)				
20 u/ml, 2 ml	00469-2900-00	4.51	3.59	AP
2 ml	00469-0420-00	8.60	5.55	AP
(Parke-Davis) *See PITRESSIN*				
VASOSULF (Ciba Ophth)				
phenyleph/sulfacet sod				
GTT, OP, 0.125%-15%,				
5 ml	00058-2563-05	8.50	7.75	
15 ml	00058-2563-15	12.54	10.45	
(Southwood)				
[illegible]				
GTT, OP, 0.125%-15%,				
5 ml	58016-6878-01	11.81		
VASOTATE (Major)				
acetic acid				
GTT, OT, 2%, 15 ml	00904-5816-05	3.75		AT
VASOTATE HC (Major)				
acetic acid/hc				
GTT, OT, 2%-1%, 10 ml	00904-5818-10	6.15		AT
VASOTEC (Merck)				
enalapril maleate				
SEE SECTION 4 FOR COLOR PHOTO				
TAB, PO, 2.5 mg, 100s ea	00006-0014-68	71.74	57.41	
100s ea UD	00006-0014-28	76.65	60.44	
(BULK PACKAGE)				
2.5 mg, 1000s ea	00006-0014-82	717.73	574.18	
(UNIT OF USE, 12X90)				
2.5 mg, 1080s ea	00006-0014-44	776.20	620.16	
(UNIT OF USE, 12X180)				
2.5 mg, 2160s ea	00006-0014-90	1550.41	1240.33	
(BULK PACKAGE)				
2.5 mg, 10000s ea	00006-0014-87	7177.25	5741.80	
5 mg, 100s ea	00006-0712-68	91.18	72.94	
100s ea UD	00006-0712-28	94.88	75.90	
(BULK PACKAGE)				
5 mg, 1000s ea	00006-0712-82	911.85	729.48	
(UNIT OF USE, 12X90)				
5 mg, 1080s ea	00006-0712-44	984.83	787.94	
(UNIT OF USE, 12X180)				
5 mg, 2160s ea	00006-0712-90	1969.83	1576.00	
4000s ea	00006-0712-81	3647.43	2917.94	
(BULK PACKAGE)				
5 mg, 10000s ea	00006-0712-87	9118.59	7294.87	
10 mg, 100s ea	00006-0713-68	95.74	76.59	
100s ea UD	00006-0713-28	99.53	79.62	

1-800-624-0152 D-5

FLORIDA INFUSION CHEMONET

DECEMBER 1994

Thanking You for a Great Year in 1994

Joins in Wishing you a Happy Holiday Season
and a Prosperous New Year

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PRICE LIST

TRACE MTE→ CONC 10ML	12/BOX		14.30
TRANSFER EXT.SET W/MINI SPIKE 50/BOX			147.50
TRANSPORE TAPE 1X10Y	12/BOX	1527	15.95
TRANSPORE TAPE 2X10Y	6/BOX	1527	15.95
TRANSPORE TAPE 3X10Y	4/BOX	1527	15.95
TRECATOR-SC 250MG TABLETS	100/BTL		140.72 *
TRIAMCINOLONE ACETONIDE 40MG/ML 5ML MDV		C4	7.40 *
TRICHOPHYTON SKIN TEST 100/80 5ML VIAL			17.70 *
TUBERCULIN PPD TINE TEST 25/PK			32.79 *
TUBERSOL 5 TU-10 TEST 1ML			8.50 *
TUBERSOL 5 TU-50 TEST 5ML			18.22 *
TUBEX INJECTOR			3.75
TYLENOL EXTRA STRENGTH CAPLETS 100/BTL			7.66
TYLENOL EXTRA STRENGTH CAPLETS 1/BTL			12.25
TYLENOL LIQUID EXTRA-STRENGTH 8OZ			5.41
UNASYN 1.5GM VIAL	10/BOX		60.46 *
UNASYN 3.0GM VIAL	10/BOX		117.14 *
UNASYN 2.0GM VIAL ADD-VANTAGE	10/BOX		121.82 *
UNDERPADS, DISPOSABLE 17.5 X 24 300/CS			26.80
UNI-SOLVE ADHESIVE REMOVER WIPES 30/BOX			8.10
URACYL MUSTARD 1MG CAPS	100/BTL		61.18 *
URETHRAL CATH. TRAY W/16FR CATH			1.91
VACUTAINER LUER ADAPTER MS 100'S BD7295			26.95
VACUTAINER LUER ADAPTER S/S 100'S BD5733			19.37
VACUTAINER, BLUE TOP 4.5ML 100'S BD6418			17.25
VACUTAINER, COLLECTION SET 30"S BD7253			46.06
VACUTAINER, COLLECTION SET 30"S BD7255			46.06
VACUTAINER, COLLECTION SET 30"S BD7255			46.06
VACUTAINER, GREEN 10ML 100'S RD6486			16.25
VACUTAINER, NEEDLE 21X1 100'S BD7512			16.40
VACUTAINER, NEEDLE 22X1 100'S BD7510			16.40
VACUTAINER, PURPLE 5ML 100'S DD6452			25.96
VACUTAINER, PURPLE 7ML 100'S DD6460			35.50
VACUTAINER, RED SET 9.5ML 100'S BD6410			35.23
VACUTAINER, RED TOP 10ML 100'S BD6441			35.50
VALIUM 10MG TABLETS 100'S		C4	91.58 *
VALIUM 10MG/2ML SYRINGE 10/BOX		C4	53.08 *
VALIUM 5MG/ML 10ML MDV		C4	17.04 *
VANCOMYCIN 1000MG VIAL			8.40 *
VANCOMYCIN 1GRAM ADD-VANTAGE	10/BOX		80.68 *
VANCOMYCIN 500MG VIAL			38.28 *
VANCOMYCIN 500MG VIAL			4.20 *
VASELINE GAUZE 3" X 9" 50'S			39.60
VELBAN 10MG VIAL LILLY			32.40 *
VENI-GARD, I.V. DRESSING #7644431 100/BX			56.80
VENI-GARD, I.V. DRESSING #7504181 25/BX			13.96
VENTOLIN SOLUTION INHALANT 20ML			10.86 *
VEPESID (VP-16) 100MG VIAL			112.55 *
VEPESID (VP-16) 150MG 7.5ML VIAL			170.34 *
VEPESID (VP-16) 1GRAM VIAL			1078.80 *
VEPESID (VP-16) 300MG VIAL			553.80 *
VEPESID 50MG CAPS 20'S			572.12 *
VERAPAMIL 2ML SDV	5/BOX		2.41 *
VERSED 1MG/ML 10ML VIAL	10/BOX	C4	143.56 *
VERSED 1MG/ML 2ML VIAL	10/BOX	C4	37.61 *
VERSED 1MG/ML 5ML VIAL	10/BOX	C4	81.40 *
VERSED 5MG/ML 10ML VIAL	10/BOX	C4	653.13 *
VERSED 5MG/ML 2ML VIAL	10/BOX	C4	81.40 *
VERSED 5MG/ML 2ML VIAL	10/BOX	C4	145.56 *
VERSED 5MG/ML 5ML VIAL	10/BOX	C4	345.75 *
VESTAL LOTION SOAP QUART			11.18
VIDEX (DDI) 100MG TABLETS	60/BTL		78.88 *
VINBLASTINE LIQUID MDV 10MG			11.60 *
VINBLASTINE LYOPH. POWDER 10MG VIAL			9.80 *
VINBLASTINE POWDER 10MG VIAL		CETUS	10.40 *
VINCASAR (VINCRISTINE) 1MG VIAL			8.20 *
VINCASAR (VINCRISTINE) 2MG VIAL			13.80 *
VINCRISTINE SOLUTION 1MG VIAL			6.50 *
VINCRISTINE SOLUTION 2MG VIAL			11.00 *
VISTARIL 25MG/ML 10ML MDV			11.35 *
VISTARIL 50MG/ML 10ML MDV			17.72 *
VIT B COMPLEX WITH C & B12 10ML MDV			10.38
VUMON 50MG/5ML AMPULE			125.12 *
WALEMED 35C PUMP W/BATTERY, BELT & POUCH			1995.00
WARM GEL PACK 6 X 6	40/CASE		42.00
WELLBUTRIN 100MG TABS 100/BTL			66.30 *
WYCILLIN 1,200,000U TUBEX	10X1ML		42.45 *
WYCILLIN 2,400,000U SYRINGE	10X4ML		90.36 *
WYCILLIN 600,000U TUBEX	10X1ML		25.46 *
WYDASE SOLUTION 150 USP 15ML VIAL			6.25 *
XYLOCAINE 0.5% 50ML MDV			3.24
XYLOCAINE 1% 10CC MDV	5/BOX		3.27 *
XYLOCAINE 1% 10ML SDV 5'S			20.11
XYLOCAINE 1% 25ML MDV			1.79
XYLOCAINE 1% 2ML AMPULES	10/BOX		12.56
XYLOCAINE 1% 50ML MDV			2.07
XYLOCAINE 1% 50C VIALS 10/BOX			16.13 *
XYLOCAINE 1% AMPULE 5ML	10/BOX		14.30
XYLOCAINE 1% 5ML AMPULES	10/BOX		13.42
XYLOCAINE 2% 50ML MDV			2.72
XYLOCAINE 2% JELLY 30GM TUBE			12.23
XYLOCAINE 4% TOPICAL SOLUTION 50ML			12.59
XYLOCAINE INJ AMPULE 1% 5ML			0.49
XYLOCAINE INJ 0.5% 50ML SDV			8.15
XYLOCAINE VISCOUS 2% 100ML			12.42
ZANOSAR (STREPTOZOCIN) 1GM VIAL			52.89 *
ZANTAC 150MG TABLETS	200/BTL		90.94 *
ZANTAC I.V. 50MG/2ML SDV 10/BOX			35.12 *
ZANTAC PRE-MIX 50MG/50ML	24/CASE		134.92 *
ZINACEF 1.5GM VIAL 25/BOX			302.41 *
ZINACEF 7.5GM BULK PACK 6/BOX			367.60 *
ZINACEF 750MG VIAL 25/BOX			155.00 *
ZOFRAN 4MG TABLETS 3/PK			28.16 *
ZOFRAN 4MG TABLETS 30/BTL			277.66 *
ZOFRAN 8MG TABLETS 3/PK			47.36 *
ZOFRAN 8MG TABLETS 30/BTL			463.09 *
ZOFRAN INJECTION 2MG/ML 20ML MDV			194.52 *
ZOFRAN INJECTION 2ML VIAL 5/BOX			89.00 *
ZOLADEX 3.6MG SYRINGE			397.50 *
ZONAS TAPE 1" X 10 YARDS	12/BOX	5104	10.96
ZONAS TAPE 2" X 10 YARDS	6/BOX	5106	10.96
ZONAS TAPE 3" X 10 YARDS	4/BOX	5107	10.96
ZOSTRIX CREAM 45GRAM TUBE			18.61 *
ZOSYN 3.375GM VIAL	10/BOX		130.30 *
ZOSYN 4.5GM VIAL	10/BOX		172.72 *
ZOVIRAX 200MG CAPSULES	100/BTL		42.65 *
ZOVIRAX 400MG TABLETS	100/BTL		167.00 *
ZOVIRAX 500MG/10ML VIAL	10/BOX		424.15 *
ZOVIRAX 800MG TABLETS	100/BTL		209.62 *
ZOVIRAX OINTMENT 3% 30GM TUBE			13.62 *

TERMS & CONDITIONS

TERMS

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FREIGHT

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DAMAGES

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RETURN GOODS POLICY

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Items Shipped In Error.
Full credit. We will refund freight expenses.

Overstock Items.
A 10% processing fee will be applied. Dated products must be received with at least 4 months shelflife. Products must be shipped prepaid. To comply with the Drug Marketing Prescription Act, all items returned for restock must be guaranteed to have been stored under sanitary conditions and within the appropriate temperature and humidity requirements.

Returned Items.
Outdated goods must be returned within 6 months after the expiration date. A 15% processing fee will be applied to the amount of credit obtained by the manufacturer.

Non-Returnable Merchandise.
a. Refrigerated products.
b. Expired products retained for more than 6 months past the date of expiration.
c. Items not returnable to the original manufacturer.

FLORIDA INFUSION

* NEXT DAY AIR DELIVERY

1-800-624-0152

FLORIDAINFUSION CHEMONET

DECEMBER 1995

2 GREAT WAYS TO SAVE

The first will save you money, the second saves you time...

1. REDUCED PRICES

FloridaInfusion, continuing in its role as the price leader in the delivery of pharmaceuticals and supplies to the Oncology Practitioner, is pleased to announce, until further notice, lower prices on the following drugs:

ZOFRAN	2mg/mL	20mL	$166.00/vial
ZOFRAN	32mg/mL	50mL	$125.00/bag
KYTRIL		1mg	$117.00/vial
FLUDARA		50mg	$152.00/vial
ADRIAMYCIN PFS		200mg	$258.00/vial
DOXORUBICIN	solution	200mg	$240.00/vial
DOXORUBICIN	powder	50mg	$52.00/vial
MITOMYCIN		5mL	$98.00/vial
MITOMYCIN		20mL	$309.00/vial
NAVELBINE	10mg/mL	1mL	$38.25/vial
NAVELBINE	10mg/mL	5mL	$191.25/vial
5-FU	Solopak	500mg	$79/vial
5-FU	Solopak	5gram	$7.25/vial
LEUCOVORIN		100mg	$3.75/vial

2. AUTOMATIC FAX ORDER SYSTEM

To provide you greater convenience, and to save you time and money, we would like to invite you to place your orders via fax using our 800 line. Of course your account manager or customer service representative is still available to assist you at any time. Take advantage of the following important benefits:

- **Provides a permanent record of your order.**
- **Fax at your convenience, anytime night or day.**
- **Cut and copy the standard forms on pages 7 & 8.**

1-800-624-0152

15

PRICE LIST

VANCOCIN 1GRAM LILLY	1s/BOX	143.00
VANCOMYCIN 500MG VIAL		7.95
VANCOMYCIN 1GRAM ADD-VANTAGE	10/BOX	78.10
VANCOMYCIN 500MG VIAL		39.28
VANCOMYCIN 1000MG VIAL		73.95
VARIVAX .5ML SDV (CHICKEN POX)		44.50
VARIVAX .5ML SDV (CHICKEN POX)	10/BOX	435.00
VELBAN 10MG VIAL LILLY		35.67
VENTOLIN SOLUTION INHALANT 20ML		19.86
VEPESID (VP-16) 500MG VIAL		553.65
VEPESID (VP-16) 1GRAM VIAL		1078.20
VEPESID (VP-16) 150MG 7.5ML VIAL		170.24
VEPESID (VP-16) 100MG VIAL		109.19
VEPESID 50MG CAPS 20'S		589.29
VERAPAMIL 2ML SDV	5/BOX	2.45
VERSED 5MG/ML 10ML VIAL	10/BOX	C4 151.90
VERSED 1MG/ML 2ML VIAL	10/BOX	C4 38.66
VERSED 2MG/ML 5ML VIAL	10/BOX	C4 65.07
VERSED 5MG/ML 10ML VIAL	10/BOX	C4 632.07
VERSED 5MG/ML 1ML VIAL	10/BOX	C4 94.92
VERSED 5MG/ML 2ML VIAL	10/BOX	C4 151.90
VERSED 5MG/ML 5ML VIAL	10/BOX	C4 189.35
VESTAL LOTION SOAP QUART		11.50
VIDEX (DDI) 100MG TABLETS	60/BTL	81.26
VINBLASTINE LIQUID MDV 10MG		31.60
VINBLASTINE LYOPH POWDER 10MG VIAL		9.60
VINCRISTINE SOLUTION 1MG VIAL		5.50
VINCRISTINE SOLUTION 2MG VIAL		9.90
VISTARIL 25MG/ML 10ML MDV		11.35
VISTARIL 50MG/ML 10ML MDV		17.72
VIT B COMPLEX WITH C & B12 10ML MDV		7.25
YUMON 50MG/5ML AMPULE		13.015
WALKMED 150 PUMP W/BATTERY, BELT & POUCH		1995.00
WELLBUTRIN 100MG TABS 100/BTL		48.85
WYCILLIN 1,200,000U TUBEX	10X1ML	43.43
WYCILLIN 2,400,000U SYRINGE	10X5ML	90.36
WYCILLIN 600,000U TUBEX	10X1ML	25.48
WYDASE SOLUTION 150 USP 15ML VIAL		8.65
XANAX 1 0MG TABLETS 100/BOTTLE	C4	88.83
XYLOCAINE 0.5% 50ML MDV		3.40
XYLOCAINE 1% 10CC MDV	5/BOX	7.63
XYLOCAINE 1% 10ML SDV 5'S		21.72
XYLOCAINE 1% 20ML MDV		1.88
XYLOCAINE 1% 50ML MDV		3.12
XYLOCAINE 1% 5CC VIALS 10/BOX		16.78
XYLOCAINE 1% AMPULE 2ML	10/BOX	16.96
XYLOCAINE 2% 50ML MDV		3.91
XYLOCAINE 2% JELLY 30GM TUBE		12.81
XYLOCAINE 4% TOPICAL SOLUTION 30ML		13.22
XYLOCAINE INJ. 0.5% 10ML SDV		6.45
XYLOCAINE VISCOUS 2% 100ML		14.10
ZANOSAR (STREPTOZOCIN) 1GM VIAL		57.60
ZANTAC I.V. 50MG/2ML SDV	10/BOX	24.12
ZANTAC I.V. 50MG/2ML 6ML MDV		9.75
ZANTAC PRE-MIX 50MG/50ML	24/CASE	174.12
ZINACEF 1.5GM VIAL 25/BOX		308.43
ZINACEF 7.5GM BULK PACK 6'S/CS		365.69
ZINACEF 750MG VIAL 25/BOX		155.00
ZINECARD 250MG VIAL		107.00
ZINECARD 500MG VIAL		214.00
ZOFRAN 4MG TABLETS 30/BTL		209.18
ZOFRAN 4MG TABLETS 3/PK		20.75
ZOFRAN 8MG TABLETS 30/BTL		485.76
ZOFRAN 8MG TABLETS 3/PK		49.37
ZOFRAN INJECTION 2MG/ML 20ML MDV		166.00
ZOFRAN INJECTION 2ML VIAL 5/BOX		96.65
ZOFRAN PREMIXED 32MG/50ML D5W	6/CS	750.00
ZOLADEX 3.6MG SYRINGE		290.00
ZOSTRIX CREAM 60GRAM TUBE		18.43
ZOSTRIX HP CREAM 30Z. TUBE		31.53
ZOSYN 3.375GM VIAL	10/BOX	130.00
ZOSYN 4.5GM VIAL	10/BOX	173.75
ZOVIRAX 10MG/G VIAL	10/BOX	350.21
ZOVIRAX 200MG CAPSULES	100/BTL	85.96
ZOVIRAX 400MG TABLETS	100/BTL	173.10
ZOVIRAX 500MG/10ML VIAL	10/BOX	441.16
ZOVIRAX 800MG TABLETS	100/BTL	319.20
ZOVIRAX OINTMENT 5% 3GM TUBE		14.17

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b. Expired products retained for more than 6 months past the date of expiration.
c. Items not returnable to the original manufacturer.

FLORIDA INFUSION

TAP: The Total Package

Lupron vs. Zoladex Present RTP Comparison on typical 101 kit order

Lupron Depot			
AWP		$ 52,078.63	
38 kits of 7.5 mg	$ 14,107.50		
21 kits of 22.5 mg	$ 23,129.19		
Total Cost		$ 37,236.69	
RTP			$ 14,841.94
Zoladex			
AWP		$ 41,461.51	
38 kits of 3.6 mg	$ 9,609.06		
21 kits of 10.8 mg	$ 15,724.17		
Total Cost		$ 25,333.23	
RTP			$ 16,128.28
RTP Comparison Fav/(Unfav)			$ (1,286.34)

Hit 'em With The Best Shot

TAP Pharmaceutical Products Inc.

TAP-BLI 0016887
CONFIDENTIAL

2-27-02

E, EJ E-2

TAP: The Total Package

Lupron vs. Zoladex New Pricing Comparison

Lupron Depot 7.5 mg

Units	AWP	Cost	Discount	RTP
1 to 11	$515.63	$412.50	0.0%	$103.13
12 to 23	$515.63	$400.13	3.0%	$115.50
24 to 47	$515.63	$391.88	5.0%	$123.75
48 to 59	$515.63	$386.53	5.0%	$128.00
60 to 71	$515.63	$375.00	9.0%	$140.25
72 +	$515.63	$365.13	11.0%	$150.50
101 to 200	$515.63	$356.81	12.0%	$158.82

Lupron Depot 22.5 mg

Units	AWP	Cost	Discount	RTP
1 to 3	$1,546.89	$1,237.50	0.0%	$309.39
4 to 7	$1,546.89	$1,200.39	3.0%	$346.50
8 to 15	$1,546.89	$1,175.64	5.0%	$371.25
16 to 19	$1,546.89	$1,150.89	7.0%	$396.00
20 to 23	$1,546.89	$1,126.14	9.0%	$420.75
24 +	$1,546.89	$1,101.39	11.0%	$445.50
34 to 66	$1,546.89	$1,070.43	13.5%	$476.46

Zoladex 3.6 mg

Units	AWP	Cost	Discount	RTP
1 to 11	$410.51	$328.40	[illegible]	[illegible]
[illegible]	$410.51	$292.[illegible]	[illegible]	[illegible]
[illegible]	$410.51	$280.[illegible]	[illegible]	[illegible]
48 to 59	$410.51	$[illegible]	[illegible]	[illegible]
[illegible]	$410.51	$266.[illegible]	[illegible]	[illegible]
[illegible]	$410.51	$259.[illegible]	[illegible]	[illegible]
[illegible]	$410.51	$252.82	[illegible]	[illegible]

Zoladex 10.8 mg

Units	AWP	Cost	Discount	RTP
1 to 3	$1,231.53	$985.22	0.0%	$246.31
4 to 7	$1,231.53	$866.99	12.0%	$364.54
8 to 15	$1,231.53	$847.29	14.0%	$384.24
16 to 19	$1,231.53	$817.73	17.0%	$413.80
20 to 23	$1,231.53	$788.18	20.0%	$443.35
24 to 33	$1,231.53	$768.47	22.0%	$463.06
34 to 99	$1,231.53	$748.77	24.0%	$482.76

Now Available!

ONCOLOGY THERAPEUTICS NETWORK

Anzemet™

A New 5-HT$_3$ Receptor Antagonist

(dolasetron mesylate injection/tablets)
from Hoechst Marion Roussel

Excellent Efficacy and Safety Profile

Great Value!

CATALOG NUMBER	NDC	BRAND NAME	ITEM	UNIT SIZE	ORDER QUANTITY	PRICE/ UNIT	AWP
900-250	0088-1206-32	Anzemet	dolasetron mesylate	100 mg vial	1	$70.00	$149.88
970-300	0088-1203-05	Anzemet	dolasetron mesylate	100 mg tablets	5	$289.75	$330.00
970-305	0088-1203-29	Anzemet	dolasetron mesylate	100 mg tablets blister pack	5	$289.75	$330.00
970-310	0088-1203-43	Anzemet	dolasetron mesylate	100 mg tablets unit dose	10	$579.50	$660.00

Outstanding Support:

Reimbursement and Patient Assistance Program Hotline 1-888-895-2219

Call the Anzemet Hotline for help with reimbursement and patient assistance programs, Monday through Friday between 10:00 am and 6:00 pm ET.

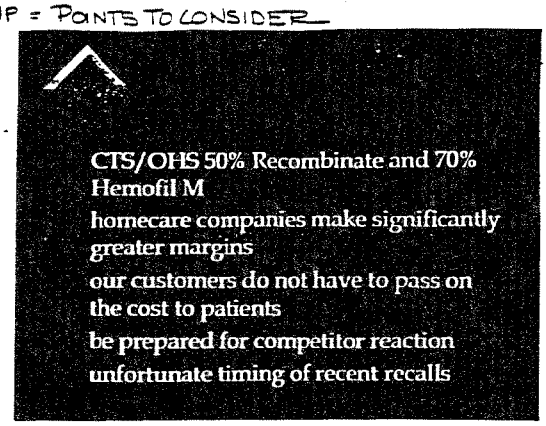
Call OTN today at 1-800-482-6700 to place your order!

E-3

CONFIDENTIAL
—BAXTER INTERNAL USE ONLY—

F-1

AWP = POINTS TO CONSIDER



- Caremark and Olsten comprise greater than 50% of our sales revenue and total unit sales for Recombinate and greater than 70% of our sales revenue and total unit sales for Hemofil M (1996 and 1997 YTD)
- Increasing AWPs was a large part of our negotiations with the large homecare companies
- Homecare companies that reimburse based on AWP make a significantly larger margin on FVIII products compared to Baxter

eg. If Caremark or Olsten reimburse at today's AWP, their margins are greater than fifty cents per unit for Recombinate and greater than forty cents per unit for Hemofil M

- Our customers do not have to pass on the increase in AWPs to patients by reimbursing at these levels
- We need to be prepared for competitors to alarm the hemophilia community that Baxter has increased ASP and AWP!
- We need to stress that we witheld from increasing prices during product shortages in 1996 and now even though the prices increase seems untimely, it is necessary and has been postponed as long as possible
- Baxter has been a leader in cost containment by keeping prices down - perhaps homecare companies, treatment centers, and insurance companies need to also do their fair share

F 2

Christopher Cheney

Bayer

08/07/97 01:15 PM

Pharmaceutical Division

To: Brian Shortell/WESTH/PH/US/BAYER
cc:
Subject: Re: Recombinate AWP Change

FYI ... it looks like if the reports are true we will need to follow suit.

---------- Forwarded by Christopher Cheney/BAYER-US-NOTES on 08/07/97 01:13 PM ----------

David Mahoney
08/07/97 12:19 PM

To: Christopher Cheney/BAYER-US-NOTES
cc:
Subject: Re: Recombinate AWP Change

Chris, if Baxter has increased their AWP then we must do the same. Many of the Homecare companies are paid based on a discount from AWP. If we are lowed than Baxter then the return will be lower to the HHC. It is a very simple process to increase our AWP, and can be done overnight. Lets talk about this next week at our meeting in Old Saybrook.
08/06/97 06:35 AM

Christopher Cheney

Bayer

08/06/97 06:35 AM

Pharmaceutical Division

To: Brian Shortell/WESTH/PH/US/BAYER
cc: Carole Guthrie/WESTH/PH/US/BAYER, David Mahoney/BAYER-US-NOTES, Terry Tenbrunsel/BAYER-US-NOTES
Subject: Recombinate AWP Change

Carole reports that a rep has heard that Baxter recently increased the AWP for Recombinate from $1.18 to $1.24. Do we have any means for verifying this information? Secondly if the info is correct would it be possible for us to match their increase? Would you be able to comment on the pro's and con's of a change to our AWP?

Call me when you get a chance.

F-3

SmithKline Beecham
Pharmaceuticals

MEMORANDUM

Oncology and Specialty Products Business Unit

March 21, 1996

TO: R. de Souza

cc: M. Davis
R. Van Thiel

FROM: D. Tasse

RE: Kytril Price Increase

I recommend a 4.8% price increase effective March 25, 1996 for all Kytril presentations. This is in repose to a Glaxo Wellcome price increase of 4.8% for Zofran effective March 8, 1996.

The following are the revised prices for wholesalers and oncology distributors:

	FORM	WAC	AWP
Wholesalers:	1mg/ml vial	139.17	173.95
	1mg 2's tablet	66.02	82.55
	1mg 20's tablet	660.24	825.30
Oncology Distributors:	1mg/ml vial	122.47	173.95
	1mg 2's tablet	62.72	82.55
	1mg 20's tablet	627.23	825.30

0321b.doc

Verbal approval from Richard de Souza attested by [signature]

SBCC 0743

AA 000529

Venoglobulin-S 5% Solution Solvent Detergent
*** New ASP = $76.15 / gram**

NDC Number	Item Description	AWP Pack Price	AWP Eff. Date
49669-1612-1	Soln, 5%, 50mL, 2.5g, ea, w/ IV set	$ 190.38	6/16/94
49669-1613-1	Soln.,5%, 100mL, 5.0g, ea, w/ IV set	$ 380.75	6/16/94
49669-1614-1	Soln., 5%, 200 mL, 10.0g, ea, w/ IV set	$ 761.50	6/16/94

Published AWP's for competitive products are as follows:
(Reference: Average AWP per 1994 Redbook)

Cutter	Gamimune N 5%	$ 57.12/ g	
Cutter	Gamimune N 10%	$ 75.00/ g	
Baxter	Gammagard S/D	$ 64.00/ g	*List Price/ Cust. Srvc
Sandoz	Sandoglobulin	$ 42.00/ g	
ARC	Polygam	$? / g	
Immuno	Iveegam	$ 65.00/ g	
Armour	Gammar IV	$ 62.00/ g	
Alpha	Venoglobulin-I	$ 47.00/ g	NOW ↑ $60.82/ g
Alpha	Venoglobulin-S	$ 65.00/ g	NOW ↑ $76.15/ g

Pharmacy billing and management services can bill for product based on the published AWP and thereby net incremental margin with Venoglobulin-S usage. Margin for the pharmacy is the difference between AWP and acquistion cost ($76.15/ g -$30/ g = $46.15/ g margin). Good luck in capturing new homecare/clinic accounts!

BAY005297

Gamimune®N Alternate Site Strategy

Reimbursement

F-5

		Distributor Acquisition Price	A.W.P.	Spread
Bayer	Gamimune®N 10%	$33.60	$75.00	$41.40
Alpha	Venoglobulin S 10%	$29.00	$80.00	$51.00
Baxter	Gammagard	$23.75	$64.00	$40.25
Centeon	Gammar P	$22.00	$68.00	$46.00
Red Cross	Polygam S/D	$21.00	$58.00	$37.00

F6

alpha® THERAPEUTIC CORPORATION

INTEROFFICE CORRESPONDENCE

TO: ATC Sales Force
ATS Sales Force
P. DeHart
D. Flanaghan
P. Gatto
J. Gross
G. Mull
J. Brown

FROM: Christine Chow

DATE: 19 September, 1996

RE: New AWP's

Bayer increased the AWP for Gamimune® N 10% from $75 per gram to $90.00 per gram beginning August, 1996. These increases were published in the August 96 Update of the Red Book. NDC numbers were changed to reflect Bayer's corporate identity numbering system. Please see attached page from the Red Book.

Alpha has increased our AWP for Venoglobulin®-S 5% and Venoglobulin®-S 10%. Effective 16 September 1996, our published Red Book Price is:

	Old AWP	New AWP
Venoglobulin-S 5%	$76.15/ gram	$ 90/ gram
Venoglobulin-S 10%	$80/ gram	$ 95/ gram

These new prices have been submitted to the Red Book and MediSpan and can be used for out-patient billing purposes. Please feel free to call if you have additional questions.

Very Best Regards, Chris

cc: Management Committee
R. Mamidi
S. Tonetta, Ph.D.
G. Chan
S. Wada

F-7

Baxter

Interoffice Memorandum – For Internal Use Only

To: Pete O'Malley

Date: June 11, 1996

cc: Larry Guiheen
Matt Likens
John Sonnier

From: Kyle A. Bush

Subject: AWP/WAC

Attached is a memo from one of our customers voicing a concern about the reimbursement levels of Gammagard S/D. Reimbursement for Gammagard S/D in Florida is significantly lower than any of the other IGIVs.

Reimbursement for IGIVs is based on either AWP (+/- a percentage depending on the state), or wholesale acquisition cost (WAC) + 8%. (WAC is used as the method of reimbursement in TX, RI, MA, MD, FL, CO, AL).

Walter has provided us with WAC prices for several IGIVs..

Ven S 10%	Ven S 5%	Gam N 10%	Gam P-IV	Poly S/D	Gam S/D
$71.26 g	$67.76	$67.76	$51.89	$51.62	$38.09

This price is being promoted by certain manufacturers sales force as a financial incentive to use their product **The deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers.**

6/17

- Will raise AWP for Ec/SD by 15%
- Review re:
  - Nanofiltration - SD Process
  - HIV antigen - R+D
  - Pull off field
- Will try to implement Q3 1996

F8

Baxter

Interoffice Memorandum - For Internal Use Only

To: Sales Managers
Biotech Sales
Hemophilia Sales

Date: August 6, 1997

cc: Brad Bridges Pete O'Malley
L.Cunningham Steve Finney
Jim Post Judy Reuter

From: Kyle Bush

Subject: AWP History

Attached is a 1997 AWP history update for all IGIV products. Under the "1997 AWP column", the **BOLDED** entries represent recent increases.

We are very aware of the current AWP increases in the market place and the potential impact that coul have on alternate site sales for Gammagard S/D. We have a strategy to raise AWP's for Hyland's products and will proceed when the timing is right. Specifically, we can increase AWP's proportionat to the average ASP increase for a specific product line. Or, we can justify an AWP increase if our internal investments have increased; i.e. PCR testing, packaging improvements, HIV/HCV antigen testing, capacity improvements, etc...

We increased the AWP for Gammagard S/D by 15% in October 1996. We will look at Gammagard S/I again in Q4 - 97 and see if the timing (criteria mentioned above has been met) is right for another AWI increase.

F-9

To: Scott Haviland

From: David Cory

Date: October 27, 1994

Re: Zofran Pricing Recommendation

The following Zofran pricing position incorporates comments made by members of the pricing team from the original pricing recommendation. Chuck has spoken to Jim Daly and plans to bring this recommendation to the pricing committee meeting on November 4, 1994.

Please let me know if you have any questions.

cc: C. Bramlage

Command 15-20% Price Premium

Introduction

Market share for Kytril in the clinic segment for the week ending 9/30/94 was 36% of units. The cumulative penetration for Kytril in the clinic segment for fiscal 94/95 is 29% (market research DDD). Although internal pricing studies projected that Kytril penetration would not reach this level until 12 to 18 months following launch, this level of Kytril unit share has been consistent over a six week period. The clinic contribution to the CIE market is currently 35% or approximately $100MM in available antiemetic dollars per year. The Zofran pricing plan identifies 25% in cumulative Kytril unit sales as a trigger point at which time Glaxo Inc. would deliver a market response.

US 29%

Discussion

Physician reimbursement for the administration of intravenous oncology drugs is based on the spread between acquisition cost and the AWP. The typical spread between the List Price and the AWP in the industry is either 16 2/3% or 20%. The majority of agents in the oncology market carry a 20% AWP. This allows the oncologist to be compensated for the cost of the intravenous drug administered as Medicare reimburses at 80% of the AWP. The administration of intravenous agents in the outpatient or clinic setting is almost exclusive to the oncology practice.

SKB's clinic promotion has been based on a therapeutic equivalency campaign with significant reimbursement advantages in favor of Kytril. The current reimbursement spread favors Kytril at $18.80 per single-dose vial compared to Zofran at $-0.89 per 32mg dose per patient.

25%

	Net Wholesale	Purchase Vial	AWP Vial	Purchase Dose	80% AWP/Dose	80% AWP/Vial	Reimbursement Spread/Patient
Kytril	$132.80	$114.00	$166.00			$132.80	$18.80
Zofran	$178.97	$172.92	$214.76	$138.39	$137.45		$-0.89

20%

Because Kytril is available in a single dose presentation, the complete vial may be billed for reimbursement. Zofran, as a multi-dose presentation, may only be billed on a milligram basis for the dose administered. Kytril carries a 20% spread between List Price and AWP compared to Zofran which carries a 16 2/3% spread providing SKB with a significant advantage in the clinic setting with respect to reimbursement.

Pharmaceutical companies were examined which currently have agents in the oncology class. The following examples illustrate that these agents carry a 20% AWP.

Company	Agent		List Price	AWP	Spread
Lederle	Novantrone 2mg/mL	10ml	$494.94	$616.18	20%
Adria	Adriamycin 2mg/ml	100ml	$540.95	$676.19	20%
Bristol	Platinol AQ 1mg/mL	50ml	$129.62	$162.75	20%
SKB	Kytril 1mg/mL 1ml		$132.80	$166.00	20%

Recommendation

In order to balance the reimbursement spread which currently exists between Zofran and the market in which it competes, one of the two scenarios which follow are recommended:

Recommendation #1

- 4.5% price increase $178.97 to $187.02 224.42
- Increase AWP 16 2/3% to 20% ~~20%~~ $214.76 to $233.78 (8.5%)
- 3% Wholesaler Rebate (11/14/94 - 1/31/95) $187.02 to $172.92 (chargeback) $172.92 to $167.31 (rebate)

25%

	Net Wholesale	Purchase Vial	AWP Vial	Purchase Dose	80% AWP/Dose	80% AWP/Vial	Reimbursement Spread/Patient
Kytril	$132.80	$114.00	$166.00			$132.80	$18.80
Zofran	$187.02	$167.31	$233.78	$133.84	$149.62		$15.77
	197.12	167.73	224.92	133.94	143.07		9.23

9.23

This program would provide a reimbursement spread of ~~$15.77~~ for a 32mg dose of Zofran. This would also incentivize the clinic segment of the business to utilize the approved 32mg dose of Zofran as reimbursement is provided on a milligram basis. Because the majority of the clinic business is price protected at $172.92 through 12/95 the net discount is only 3% off current contracted prices.

Recommendation #2

- 4.5% price increase $178.97 to $187.02 (73.12)
- 7% Wholesaler Rebate (11/7/94 - 1/31/95) $187.02 to $172.92 (chargeback) (10.82) $172.92 to $159.82 (rebate)

	Net Price	Purchase Vial	AWP Vial	Purchase Dose	90% AWP Dose	80% AWP Dose	Reimbursement Spread Dose
Kytril	$132.80	$114.00	$166.00			$132.80	$18.80
Zofran	$187.02	$159.82	$224.43	$127.86	$143.64		$15.77

This program would provide a reimbursement spread of $15.77 for Zofran. Again, the program would incentivize the use of the approved 32mg dose as reimbursement is provided for milligrams administered. The net discount from price protection at $172.92 to $159.82 would be 7%.

The impact of these programs will provide a level platform for Zofran sales promotion within the oncology clinics relative to Kytril. The recommended multi-tiered modification to current promotion, should also provide an immediate resultant impact to weekly unit sales without being easily intelligible by SKB as to the means by which this was achieved. Thus, providing additional time before a competitive response would be delivered.

In response, SKB will likely have two options:

Option 1: Decrease the purchase price of Kytril.

Option 2: Take a price increase to raise the AWP while maintaining purchase price to generate a higher spread than $52.00.

Neither option appears advantageous for SKB. Because SKB has not reduced the price of Kytril recently and market share trend is positive, it appears they are content with current pricing strategy. A reduction in price would have a significant impact on Kytril revenues. Conversely, a price increase would be inconsistent with the price message, a marketing strategy that SKB has employed since launch.

G-1

From JSF 10/30/97

Dr. William Quan
Comprehensive Cancer Center, Inc.
c/o Salick Health Care Center, Inc.
8201 Beverly Blvd.
Los Angeles, CA. 90048-4520

Dear Willie,

A (VPR) Voluntary Price Reduction will become effective May 9, 1997. The wholesalers have been notified, however it may take two weeks to complete the transition. Pricing for direct orders are effective as of May 9,1997. This new pricing is designed to keep Salick competitive if the market place

Products		NDC#	NEW PRICES
Adriamycin RDF	10 mg	108691	$ 6.75
Adriamycin RDF	20 mg	109691	$ 13.49
Adriamycin RDF	50 mg	110679	$ 33.73
Adriamycin RDF	150 mg	111683	$101.19
Adriamycin PFS	10 mg	113691	$ 7.60
Adriamycin PFS	20 mg	114691	$ 15.20
Adriamycin PFS	50 mg	115679	$ 38.00
Adriamycin PFS	75 mg	117687	$ 57.00
Adriamycin PFS	200mg	116683	$152.00
Bleosar	15 unit	161678	$165.00
Bleosar	30 unit	163686	$330.00

If you have any questions, please don't hesitate to call me. Hope to see you in Denver.

Regards

Dan Bell
salickvp

6-2

hor: GRDERR at PN04PO
te: 10/21/97 9:22 AM
iority: Normal
O: *SGAMS at Mail_List
ubject: Market Company Alert - October 1997 Price Increase

---------- Message Contents ----------

SGAMS

FYI - Heads up. The following P&U price increases may create a spread between purchase price and Medicaid reimbursement that may create sales complaints if not resolved in a reasonable time period by customary Medicaid updates. Therefore, your action may be required in some instances if over the next few months Medicaid does not automatically pick up the price changes.

Glen

3.

---------- Forward Header ----------

Subject: Market Company Alert - October 1997 Price Increase
Author: JSHOLLEN at PN01PO
Date: 10/20/97 7:44 PM

October 20, 1997 Contracting & Pricing

TO:
* VP US Pharm Sls
* Reg Sls Dirs/PSMs
* Operations Dir
* Team Fed Govt
* HC Ed Svcs
* Therapeutic DSMs
* PSL
* Public Affairs
* Nat Cust Svc Sls Dir
* Acct Team Dirs
* Natl Acct Dirs
* Mgd HC Dirs
* Reg Acct Mgrs
* DC Reg Dir/Mgr
* Pharm Sls Spec
* Ophthalmic Reps/DSMs
* Peptide Hormone Reps
* Oncology/Aids Reps
* Uro/Derm Reps/UBCs
* Hospital Reps
* Team Kaiser
* Team Coaches/DSMs

FROM: William Hillmer, Pricing Analyst, ext. 3-8386

SUBJECT: October 1997 Price Increase - Effective October 21, 1997

Effective with the close of business hours, Monday, October 20, 1997, the Retail & Wholesale prices of many Pharmacia & Upjohn Company products will be revised.

All catalog orders received after business hours, October 20, 1997, will be invoiced at revised prices. Attached are the product families affected and their percentages. A complete reprint of the Retail and Wholesale Price Lists will be issued in January 1998. Until then, please use your January 1997 Retail and Wholesale Price lists along with all 1997 price change announcements. Within the next few days you will receive a letter detailing the revised products and their new prices.

As a courtesy, we are allowing our customers the opportunity to make a one-time buy-in purchase at old list prices if they have direct purchase history for the products with price revisions. Their one-time purchase will be limited to a two-week average supply based on their net-direct April 1997 through September 1997 purchase history.

For all our customers who have April 1997 through September 1997 direct purchase history for the products with price revisions, we will mail them a Special Buy-In Order Form the week of November 10, 1997. The Special Buy-In Order Form will indicate the maximum allotment of each product that they may purchase at old list prices. Excessive purchases will be reduced to the buy-in allotment. They must use the Special Buy-In Order Form and it must be received on or before December 10, 1997 to be invoiced at the old prices. As inventory allotments allow, their buy-in order will be shipped between the receipt of their Order Form and January 16, 1998.

Complete buy-in instructions will be provided to customers with their Special Buy-In Order Form. PSM s will receive complete Price Increase Buy-In order form packages in early November.

PRODUCT	PERCENT INCREASE
ADRIAMYCIN	6.0
ADRUCIL Injection	6.0
ALBAMYCIN Capsules	6.0
ANSAID Tablets	7.0
AZULFIDINE Tablets	10.0
AZULFIDINE En-Tabs	10.0
BLEOMYCIN	6.0
CAVERJECT Sterile Powder	5.0
CLEOCIN Vaginal Cream	7.5
CLEOCIN HCl Capsules	10.0
CLEOCIN PHOSPHATE	20.0*
CLEOCIN T Topical Solution	7.0
CLEOCIN T Topical Gel & Lotion	7.0
COLESTID Granules	7.0
COLESTID Tablets	7.0
CORTEF Oral Suspension	7.0
CORTEF Tablets	7.0
Cortisone Acetate Tablets	7.0
CORVERT Tablets	15.0
CYKLOKAPRON Ampoule	30.0
CYTOSAR-U Sterile Powder	6.0
DELTASONE Tablets	6.0
DEPO-Estradiol Sterile Solution	10.0
DEPO-MEDROL Sterile Aqueous Suspension	6.0
DEPO-PROVERA Contraceptive Injection	6.0
DEPO-PROVERA Sterile Aqueous Solution	9.0
DEPO-TESTADIOL Sterile Solution	10.0
DEPO-Testosterone Sterile Solution	10.0
DIDREX Tablets	10.0
DIPENTUM Capsules	9.0
DOSTINEX Tablets	4.0
EMCYT Capsules	6.0
ESTRING Ring	5.0
FLAVORED COLESTID Granules	7.0
GELFILM Products	9.9
GELFOAM Sterile Powder	15.0
GELFOAM Sterile Sponge	4.8
HALCION Tablets	10.0
HALOTESTIN Tablets	10.0
HEMABATE Sterile Solution	9.9
Heparin Sodium Injection	7.0
IDAMYCIN Injection	6.0
KABIKINASE Lyphilized Powder	15.0
LINCOCIN Capsules	10.0
LINCOCIN Sterile Solution	6.0
LOKTLEN Tablets	10.0
MEDROL Tablets	7.0
MICRONASE Tablets	8.0
MOTRIN Tablets	6.0
MYCOBUTIN Capsules	5.0
NEOSAR	6.0
OGEN Tablets	5.0
OGEN Vaginal Cream	5.0
ORINASE Tablets	7.0
PREPIDIL Gel	9.9
PROSTIN E2 Vaginal Suppository	50.0
PROSTIN VR PEDIATRIC Sterile Solution	20.0
PROVERA Tablets	10.0
SOLU-MEDROL	6.0
TOLINASE Tablets	7.0
TOPISAR	5.0
TROBICIN Sterile Powder	10.0
VINCASAR	6.0
XANAX Tablets	8.0
ZANOSAR Sterile Powder	10.0
ZINECARD Injection	8.0

BLEOMYCIN
Sterile Bleomycin Sulfate, USP
EQUIVALENT TO 15 UNITS BLEOMYCIN
Sterile Bleomycin Sulfate, USP
EQUIVALENT TO 30 UNITS BLEOMYCIN
CAUTION: Federal law prohibits dispensing without prescription
Pharmacia
G-3
15u $198.00
30u $396.00

FLORIDAINFUSION

SPECIAL PRICES VALID
Nov 17/97 - Nov 21/97

BLEOMYCIN

6-4

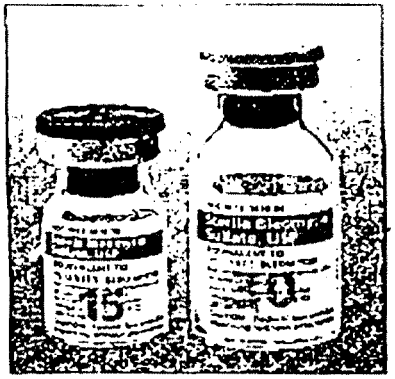
15unit ..... $175.00 ←

30unit $350.00

FLORIDA INFUSION CHEMONET

FALL 1998

BLEOMYCIN



15u $158.00

30u $330.00

G-5

DEY LABORATORIES

MEMORANDUM

TO: Sales and Marketing **cc:** R. F. Mozak

FROM: Helen Burnham

DATE: May 30, 1995

Re: **ALBUTEROL WAC PRICING**

Attached is a copy of a fax sent to all database managers to update their records with our wholesale acquisition cost (WAC) for albuterol.

As you know, the following states are now using WAC instead of AWP to calculate Medicaid reimbursement:

- Alabama
- Colorado
- Florida
- Maryland
- Massachusetts

WAC is not representative of our published wholesale list prices, but like AWP, is used for calculation of reimbursement. Our updated WAC values are in line with the Warrick WAC values provided by First Data Bank and should level the playing field for Medicaid reimbursement.

005

Please give me a call if you have any questions.

207

...25, 1996

SB SmithKline Beecham Pharmaceuticals

...Whren
Executive Vice President
Physician Reliance Network (P...)
...15 Preston Road, Ste 300
Dallas, TX 75225

Dear Bob:

The purpose of this document is to amend effective July 1, 1996 our current Kytril Agreement dated October 16, 1995 to include the following modification under Section II paragraph A:

I. SB agrees to pay PRN a rebate in the amount of $ 20.46 per Kytril vial purchased during the term of this Agreement and used in a PRN clinic provided that PRN maintains and markets Kytril as the preferred oral and injectible 5HT3 within it's owned oncology centers. This rebate will be paid on a quarterly basis to PRN.

II. SB agrees to guarantee a net price to PRN of $102.00 throughout the term of this Agreement. This net price will be exclusive of wholesaler or distributor mark up or administrative fee applied to the purchases of Kytril injection by PRN.

III. Contract expiration date stated herein shall be 12/31/97.

All other terms and conditions of our Agreement will remain in full force and effect unless inconsistent with or superseded by the terms of this Agreement.

Thank you for your continued interest in our products. If you have any questions regarding this extension please contract me at (215)751-7920.

ACCEPTED AND AGREED TO:

David Lichtenstein Date
Sr. Contract Manager
SmithKline Beecham

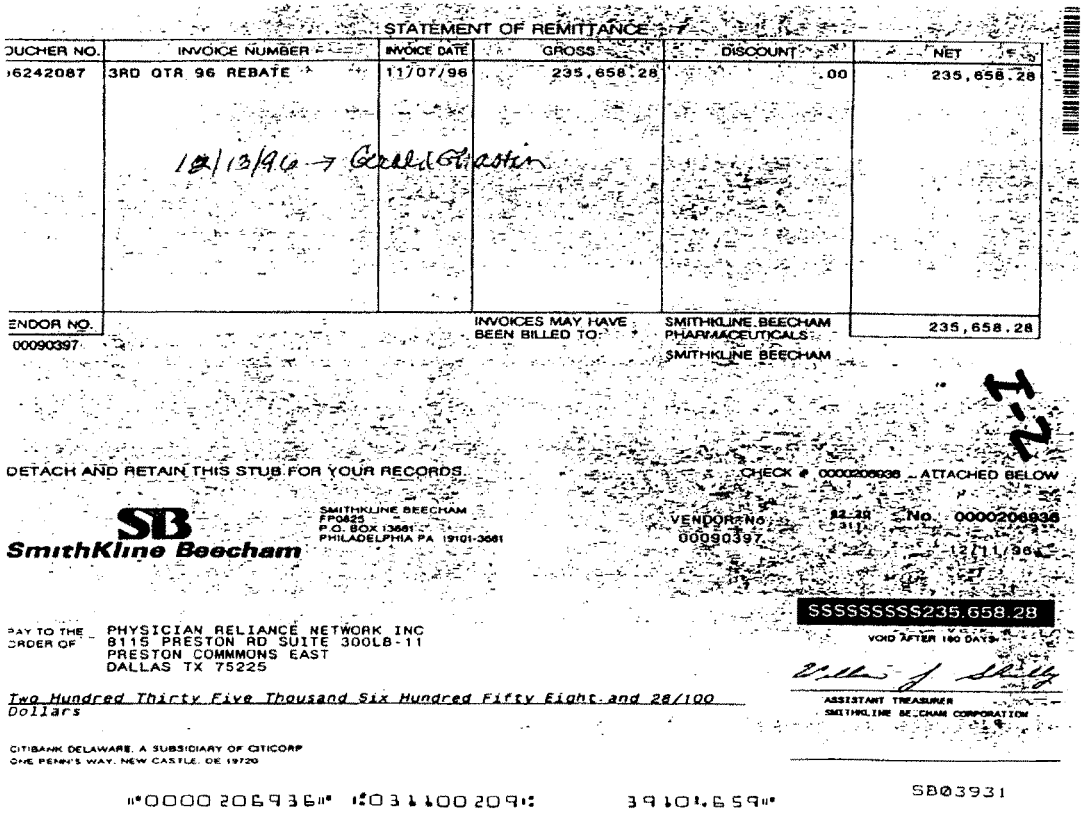
Bob Whren 7/8/96
Bob Whren Date
Executive Vice President
Physician Reliance Network

Jerry Ghastin 7/8/96.
Jerry Ghastin Date
SmithKline Beecham IHD

SB03930

H-1

208



STATEMENT OF REMITTANCE

VOUCHER NO.	INVOICE NUMBER	INVOICE DATE	GROSS	DISCOUNT	NET
6242087	3RD QTR 96 REBATE	11/07/96	235,658.28	.00	235,658.28

12/13/96 → Gerald Glaston

VENDOR NO. 00090397

INVOICES MAY HAVE BEEN BILLED TO: SMITHKLINE BEECHAM PHARMACEUTICALS SMITHKLINE BEECHAM

235,658.28

DETACH AND RETAIN THIS STUB FOR YOUR RECORDS.

CHECK # 0000206936 ATTACHED BELOW

SB SmithKline Beecham

SMITHKLINE BEECHAM
FP0425
P.O. BOX 13661
PHILADELPHIA PA 19101-3661

VENDOR NO. 00090397

82-28 311

No. 0000206936

12/11/96

$SSSSSSSS235,658.28

VOID AFTER 180 DAYS

PAY TO THE ORDER OF
PHYSICIAN RELIANCE NETWORK INC
8115 PRESTON RD SUITE 300LB-11
PRESTON COMMMONS EAST
DALLAS TX 75225

Two Hundred Thirty Five Thousand Six Hundred Fifty Eight and 28/100 Dollars

ASSISTANT TREASURER
SMITHKLINE BEECHAM CORPORATION

CITIBANK DELAWARE, A SUBSIDIARY OF CITICORP
ONE PENN'S WAY, NEW CASTLE, DE 19720

⑈0000206936⑈ ⑆031100209⑆ 39101659⑈

SB03931

[illegible]ruary 1, 1[illegible]

[illegible]on Whiteaker
[illegible]uantum Health [illegible]Resources
[illegible]90 The City [illegible]ision South
[illegible]range, CA 92[illegible]68

[illegible]David [illegible]Mahoney
[illegible]Direct
[illegible]Sales

Dear Don: BAY0 [illegible]17

As a follow up to our con[illegible]ersat[illegible]on regar[illegible]ing our special end of the year proposals the following prices and terms were offered:

1. Gamimune-N 10% promotion: 8/1-12/31/93

   A. Product will be billed at $30.00 per gram.
   B. A credit memorandum will be issued in January for $5.80 per gram retroactive to August 1, 1993.
   C. Special billing terms, less 2%, 90 days, net 91.

2. Kogenate promotion: 11/1/93-12/31/93

   A. Kogenate will be invoiced at $.82 per AHF unit.
   B. A credit memorandum will be issued in January, 1994, for $.21 per unit for all Kogenate purchased during this promotion. The following purchase orders were placed during this promotion: #12774; #12775; and #12776. These orders were for approximately 3,000,000 AHF units.

Please call me if I can provide you with any additional information.

Regards,

David P. Mahoney

6.0 REBATES

NV 0001059

6.1 Schedule A/Quarterly Performance Rebate. Purchases, net of returns, will be valued at contract price.

SCHEDULE A: QUARTERLY SANDOGLOBULIN® PERFORMANCE REBATE			
		Performance % Benefit	
Required Sandoglobulin® Purchases	Level	Sandoglobulin®	Sandostatin®
$ 0 - $150,000	Level 1	18.5%	0%
$150,001 - $200,000	Level 2	38.0%	0%
$200,001 - $250,000	Level 3	42.0%	0%
> $250,000	Level 4	46.0%	5%

Purchases, net of returns, will be valued at contract price.

6.2 Rebates will be calculated based on SPC data. The contracted account may seek amendment to these calculations provided alternate data is furnished and can be substantiated by SPC.

6.3 Rebate periods will be quarterly as follows:

Schedule A

From:	To:
October 1, 1995	December 31, 1995
January 1, 1996	March 31, 1996
April 1, 1996	June 30, 1996
July 1, 1996	September 30, 1996

MENTS:

cpd 10/13/94 EY

R94-0919 CT#MSP 04007 4-6/94

▼ PLEASE DETACH THIS STUB BEFORE DEPOSITING CHECK ▼

SANDOZ

REGULAR ACCOUNT

66-35
631

SANDOZ PHARMACEUTICALS CORPORATION
59 ROUTE 10, EAST HANOVER, NEW JERSEY 07936-1080

Wachovia Bank of North Carolina, N.A.
Winston-Salem, N. C. 27150

CHECK NUMBER
0982197

DATE	AMOUNT
10/06/94	***153,798.29

PAY TO THE ORDER OF:

CAREMARK PRESCRIPTION SERVICE
111 BARCLAY BLVD.
LINCOLNSHIRE IL 60069

Wayne R. Small

AUTHORIZED SIGNATURE

J-5

⑈0098219⑆ ⑆053100355⑆010454 001272⑈

First Class to Caremark
10/12/94 lc

Customer Name and Address:

Quantum Health Resources

6666 East 75th Street

Indianapolis, IN 46250

Attn: Director of Pharmacy

Rebate Form:

X	Check	$	24,289.56
	Credit	$	11.86
	Rx Product	$	
	OTC Product	$	
	Carryover	$	
	Carry Forward	$	

Avg. Membership/Scripts for Rebate Period:

Membership (HMO)

Scripts (MSP)

If Direct Account, are payments up to date? ___ Yes per ___ No (State Status below)

Send copy of detail sheets to the Account (your copy is automatically mailed) ☐

Make rebate payable to: If Different From Above

T.6

5-1

Bayer

Pharmaceutical Division

Internal Memorandum

DATE: October 1, 1996

TO: Chris Cheney

FROM: David Mahoney

SUBJECT: Volume Sales Opportunities - Kogenate®

cc: Jim Patchen
Jim Lamb

Our two largest Kogenate® customers, Quantum Health Resources and Caremark, have both stated that they will consider purchasing largest additional amounts of Kogenate® from now until the end of the year.

Quantum projects their recombinant factor VIII, sales to be 100mm/units in 1996. We will supply between 25 and 28/mm units of Kogenate®. They have committed 60 mm/ units to Baxter and Armour. This leaves approximately 12mm / unit up for grabs. We have an excellent chance to pick up most, or all of these 12mm / unit if we put together an attractive proposal.

I have been told that our present Kogenate® price, $ .66, is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest a price of $ .60 to $ .62 to secure this volume. From Quantum's stand point, a price off invoice, is the most desirable. We could calculate our offer in the form of a marketing grant, a special educational grant, payment for specific data gathering regarding Hemophilia treatment, or anything else that will produce the same dollar benefit to Quantum Health Resources. If we are interested in pursuing this additional volume of Kogenate® sales, I will need your input in the next 10 days. I have a meeting scheduled with Pete DeComo, Sr. VP, Operations, during the National Hemophilia Foundation Convention on October 17, 1996.

Caremark is also in the position to buy an additional 3-4 million units of Kogenate® by the end of the year. We should consider something comparable to Quantum in order to pursue this business.

Chris please get back to me with your ideas as soon as possible.

CONFIDENTIAL
COMMERICAL INFORMATION

BAY005241
BAY005242

CAREMARK

CAREMARK, INC.
Therapeutic Services Division
1127 Bryn Mawr Dr.
Redlands, California 92374
909.796.7171

Caremark, Inc.
Therapeutic Services Division

PLARS #OPS
1/5/94 Stock

PURCHASE ORDER 28411

DATE:

VENDOR: HyLand

SHIP TO: C.T.S.

ADDRESS:

ADDRESS:

CITY:

CITY:

Delivery Date: 1/5/94 Allowance: Terms: Ship Via:

Ordered by: George Harrell Vendor Contact Vendor Acct # Phase Order: ☐ YES ☐ NO

	Quantity Ordered	Quantity Received	Product Code	Manufacturer Number	Item Description	Unit Price	Unit	Total	Account Numbe
1)	224	224	CCHYP-A2CBAA		GAMMAGARD 10GM	0.00			4501-10
2)					EXP. 7/9/95 LOT # 23702 BAA				
3)									
4)									
5)					FREE GOODS				
6)									
7)									
8)									
9)									

OK to Ship
1-10-94

215

Value of Baxter's Free Goods to Caremark

1994 AWP for GAMMAGARD 10 grams

= $610.20

224 x $610.20 =

$136,684.80

J-3

ONCOLOGY PURCHASING AGREEMENT

Seller:

PHARMACIA
P.O. Box 16529
Columbus, OH 43216-6529

Buyer:

TEXAS ONCOLOGY
3320 Live Oak Street
Dallas, TX 75204

TX122
OPA

Contract Number CT0000 2210 6/1/94 - 5/31/97
(To Be Assigned By Pharmacia)
replaces CT0000 2143
@ 6/6/94

The following prices are being offered for consideration by Pharmacia (SELLER) to Texas Oncology (BUYER) under the terms and conditions outlined below, and subject to all applicable Government regulations, for the period June 1, 1994 through May 31, 1997, effective upon acceptance of this written agreement.

All invoices will be priced according to the following schedule:

PRODUCT DESCRIPTION	NDC No 0013-	UNIT SIZE	PRICE
ADRIAMYCIN RDF® (doxorubicin hydrochloride for injection USP)	1086-91	10 mg vial	$ 12.40/vial
	1096-94	20 mg vial	$ 24.80/vial
	1106-79	50 mg vial	$ 62.00/vial
	1116-83	150 mg vial	$182.28/vial
ADRIAMYCIN PFS® (doxorubicin hydrochloride injection USP)	1136-91	10 mg vial	$ 14.00/vial
	1146-94	20 mg vial	$ 28.00/vial
	1156-79	50 mg vial	$ 70.00/vial
	1176-87	75 mg vial	$105.00/vial
	1166-83	200 mg vial	$ 274.40/vial

002824

PRODUCT DESCRIPTION	NDC No 0013-	UNIT SIZE	PRICE
ADRUCIL® (fluorouracil injection USP)	1036-91	500 mg vial	$ .93/vial
	1046-94	2.5 gm vial	$ 4.42/vial
	1056-91	5 g vial	$ 6.82/vial
FOLEX PFS™ (methotrexate sodium injection USP)	2266-91	50 mg vial	$ 3.01/vial
	2276-91	100 mg vial	$ 4.14/vial
	2286-91	200 mg vial	$ 4.94/vial
	2296-91	250 mg vial	$ 7.43/vial
NEOSAR® (cyclophosphamide for injection USP)	5606-93	100 mg vial	$ 2.82/vial
	5616-93	200 mg vial	$ 4.47/vial
	5626-93	500 mg vial	$ 7.43/vial
	5636-70	1 GM	$ 11.75/vial
	5646-70	2 GM	$ 23.50/vial
VINCASAR PFS® (vincristine sulfate inj USP)	7456-86	1 mg vial	$ 5.34/vial
	7466-86	2 mg vial	$ 9.52/vial
AMPHOTERICIN-B	1405-44	50 mg vial	$ 18.75/vial

Pharmacia standard terms and conditions of sale are attached and form a part of this agreement. Payment terms for this agreement will be 2% 60 days, net 61.

Where Texas Oncology has pharmacy facilities, Pharmacia will provide Texas Oncology two sets of invoices for each order, with one being sent to the "ship to" location and the other to the "bill to" location.

Periodic price reviews will be conducted at a minimum of every 12 months, as initiated by Pharmacia or Texas Oncology. Adjustments based on market competition will be agreed upon by both parties.

Other oncology products may be added to this agreement, at a price to be negotiated between the parties, as they become available.

Pharmacia will provide Texas Oncology with a one time educational grant of $35,000 to provide systems for drug and pharmaceutical information and management.

During each year of this agreement 6/1 - 5/31, if Texas Oncology exceeds the unit purchases of doxorubicin of the preceding year (calculated in 10 mg equivalent units), Pharmacia will provide Texas Oncology with 5% of this years purchases in unit terms in free goods. These free goods will be provided in the pack desired by Texas Oncology.

This educational grant and free goods rebate should be regarded as discounts from price and all Medicare/Medicaid claims should reflect this discount.

Pharmacia and Texas Oncology will meet and negotiate in good faith to establish a joint approach to Texas Oncology's managed-care business.

This agreement contains confidential materials. The release of this information to any third party without prior written permission from Pharmacia may result in termination of agreement prices.

This agreement is not binding until it is signed by the Buyer and received and accepted by Pharmacia.

Accepted By:

Bob Whren

Bob Whren
President, Texas Oncology Pharmacy Services
Texas Oncology, P.A.

6/11/95
Date

Approved By:

Thomas J Komenda 6/20/95

Thomas J. Komenda
Director of Sales
Pharmacia

TX/oj - May 26, 1995

Pharmacia
Adria

J-4

Date

Reference

June 5, 1995

To: Dave Westaway
From: Randy Ross
Re: Texas Oncology Contract Review Meeting - June 27, 1995

In preparation for our meeting with Bob Whren on June 27, I have listed some items that we should address for the meeting.

1. **Unrestricted Educational Grant**
   - * $35,000 grant was previously provided and combined with 5% free goods to offset Chiron doxorubicin offer of $53.95 / 50 mg. versus our price of $62.00 / 50 mg. equivalent.
   - * I have requested Beth Remmenga to confirm performance to qualify for free goods.
   - * Upon receipt of Beth's information, we should determine terms to remain price competitive.
   - * In our conference call with Bob Whren last year, he did raise the question of the $35,000 in years 2 and 3 of the contract. This will be an issue to address.

2. **Pricing Adjustments**
   - * In speaking with the buyer for Texas Oncology, he indicated that he thought our Vincasar price might be a little on the high side. I asked him to provide any additional information and I am waiting for his follow up. At this time, it is below our best rebated price for the SA2 and I am inclined not to change it unless we are significantly out of line with an offer they have.

3. **Contract Terms**
   - * Bob Whren has indicated an interest in utilizing a wholesaler and has been courted by Alternate Site Distributors (ASD) of Dallas. The sticking point is that Bob is not willing to pay the wholesale up charge.
   - * Texas Oncology is also in the process of developing an online communications system for their pharmacies and offices that will eventually include inventory management and ordering. Some parts of the system are active at this time. They are using a consulting group called Access Data out of Tennessee to develop the system.

Postal address
Adria Laboratories
Post Office Box 16529
Columbus, Ohio 43216-6529
USA

Visiting address
7001 Post Road
Dublin, Ohio 43017
USA

Telephone
614-764-8100

Telex
246-620

Main Telefax
614-764-8102

4. **Toposar Addition to Contract**
   * They currently have a contract with Gensia that runs into the fall. They prefer not breaking existing contracts and I respect that.
   * We may wish to make an offer that allows us to be their designated second line source insuring that our pricing is below Gensia's. For some additional consideration, we should ask for the first right of refusal after the current contract with Gensia expires.

5. **Capitation Options**
   * Still a topic of interest with them.
   * As part of the contract review, we should offer some plans for a prospective review under a capitated rate per life or per case. Specify each parties responsibility in gathering and analyzing date. This keeps the conversation moving. By setting it up as a prospective review, we can compare potential programs to the current traditional contract without putting either party at risk.

6. **Meet with Dr. Reese**
   * Follow up on conversation that Dr. Thio had with Reese, Jones and Swain at Snowmass.
   * Dr. Reese indicated an interest in "partnering" with pharmaceutical companies but not necessarily in the Zeneca sense.
   * This is an important area and opportunity for Senior Management follow up.
   * Possibly bring both Dr. Reese and Bob Whren to Columbus for a meeting.

Dave, these are the issues that I see as most pressing at this time. I hope that you and I can discuss these no later than the Zinecard launch meeting in Orlando. I will follow up with you later this week to find a time that would be best for you. If you have any questions, please let me know.

Best Regards,

Randy Ross

cc: Ola Magnusson
T. Komenda
J. Thompson
T. Klinker
D. Marsico
B. Remmenga

J-5

AOR

American Oncology Resources

Educ. programs

March 24, 1997

John E. Thompson
National Account Director
Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Mr. Thompson:

American Oncology Resources would like to thank you again for Pharmacia & Upjohn's 1997 commitment to key medical education activities. As confirmation, I have listed below the specific details of this commitment, as well as, an invoice for that activity. Financial sponsorship of a medical education meeting can be received at the time of the meeting. As a reminder, your company is welcome to attend these meetings during designated times and present material appropriate to the discussion.

Medical Education Meeting	Date	Sponsorship
Disease Specific Task Force	*June*	*$6,750*
Disease Management Task Force	*July*	*25,500*
Research Task Force	*September*	*21,000*
50 AOR Yearbooks	*April*	*2,500*

Payment for your purchase of the AOR yearbook is due upon receipt of this invoice. Copy for the yearbook is currently being finalized and printing should be complete within the next month. As soon as they are received we will ship them to you.

Thank you again for your committed involvement with AOR during 1997. We look forward to working with you to improve and advance the care our cancer patients.

Sincerely,

Sharon Jameson, MBA, RN
Director, Medical Affairs

J-6

AOR/PHARMACIA & UPJOHN
PARTNERSHIP PROPOSAL

Elements of proposal:

1. Contract Pricing for P&U products (see Attachment I)
   - 3-year agreement
   - 3% administrative fee on all products ~~or contract~~ ($473,800 based on '97 projections).
   - CAMPTOSAR price protection thru 1997. Six month reviews after January 1, 1998.
   - Flexibility in negotiation of pricing if government intervenes in reimbursement processes.

2. **New Product Introductions**
   P&U will work with AOR on all new product introductions.

   P&U will work with AOR at introducing our LHRH to compete against Lupron/Zoladex. Our LHRH, brand name Triptorelin, will be available in late 2nd Quarter, early 3rd Quarter.

   P&U, working with AOR, would establish a pricing mechanism for Triptorelin with spreads favoring AOR versus current LHRH. Triptorelin would be a therapeutic equivalent to Lupron/Zoledex. This pricing advantage would increase profitability to AOR

3. **Medical Education Grants**

   A $55,000 grant has been committed for 1997 for the AOR Partnership for excellence package including:
   - Education/Disease Management
   - Research Task Force
   - AOR Annual Yearbook

   A $40,000 grant to sponsor the AOR monthly teleconference. This sponsorship was committed and completed in February 1997.

   Both of these grants would be committed in 1998 and future years if the partnership is agreed to.

4. **P&U Customer Development Program with AOR**

   This commitment valued at $300,000-$400,000 would include:

   a. Clinical practice improvement program (CPI).
   b. Consultation on disease management processes and principles.
   c. Research and analysis of "Best Practices" for CPI.
   d. Design Works, a P&U customized behavior change program.
   e. Other developmental customized programs for AOR. Example: Development of Internet access, coordination of AOR's Regional Marketing Directors for recruitment, patient satisfaction surveys, etc.

All of the above to be co-developed to the satisfaction of AOR and P&U.

5. **Clinical Research Trials**

Initial Phase III Protocol trial for "Oral Idamycin" in lymphomas. This trial will offer AOR $1.1M in additional revenues. Two hundred twenty-five (225) patients at $5,000 per patient.

This clinical research trial is dependent on the signing of a partnership agreement. AOR will become a "first choice" for clinical studies.

6. **Sharing of AOR Clinical Information Systems**

P&U is committed for $100,000 to AOR per calendar year to develop and share AOR Clinical Information System.

The above six items are contingent on the signing of the AOR Disease Management Partner Program. AOR's exclusive compliance to the purchase of the products listed in the contract product attachment is also necessary for the above items to be in effect.

Sheet1

			Attachment 1			
		AOR Contract Pricing Proposal, April 1997				
Product		AWP	List Price	AOR Current Price	Suggested New Contract Prices	$ Volume
Adriamycin						$ 2,123,528.00
1086-91	RDF 10 mg	$ 46.00	$ 36.80	$ 8.00	$ 7.50	
1096-91	RDF 20 mg	$ 92.00	$ 73.60	$ 16.00	$ 15.00	
1106-79	RDF 50 mg	$ 230.00	$ 184.00	$ 40.00	$ 37.50	
1116-83	RDF 150 mg	$ 676.19	$ 540.95	$ 120.00	$ 114.00	
1136-91	PFS 10 mg	$ 48.31	$ 38.65	$ 8.40	$ 7.50	
1146-91	PFS 20 mg	$ 96.63	$ 77.30	$ 16.80	$ 15.00	
1156-79	PFS 50 mg	$ 241.56	$ 193.25	$ 42.00	$ 37.50	
1176-87	PFS 75 mg	$ 362.35	$ 289.88	$ 63.00	$ 56.25	
1166-83	PFS 200 mg	$ 946.94	$ 757.55	$ 168.00	$ 150.00	
Adrucil						$ 160,427.00
7525-36	500 mg	$ 1.54	$ 1.23	$ 0.93	$ 0.93	
7525-37	2.5 gm	$ 7.69	$ 6.15	$ 4.42	$ 4.42	
7525-38	5 gm	$ 15.38	$ 12.30	$ 6.82	$ 6.82	
bleomycin						$ 1,182,348.00
1616-79	15 IU	$ 292.43	$ 233.94	$ 187.00	$ 175.00	
1616-86	30 IU	$ 584.83	$ 467.86	$ 374.00	$ 350.00	
Neosar						$ 370,575.00
7525-40	100 mg	$ 5.39	$ 4.31	$ 2.50	$ 3.00	
7525-41	200 mg	$ 10.24	$ 8.19	$ 3.50	$ 3.50	
7525-42	500 mg	$ 21.50	$ 17.20	$ 6.95	$ 5.00	
7525-43	1 gm	$ 43.01	$ 34.41	$ 11.50	$ 9.00	
7525-44	2 gm	$ 86.00	$ 68.80	$ 22.00	$ 18.00	
Toposar						$ 931,621.00
7525-45	100 mg	$ 136.49	$ 109.19	$ 19.50	$ 12.00	
7525-46	200 mg	$ 272.98	$ 218.38	$ 39.00	$ 24.00	
7525-47	500 mg	$ 565.38	$ 532.30	$ 97.50	$ 60.00	
7366-73	1 gram	$ 1,330.75	$ 1,064.60	$ 195.00	$ 120.00	
Vincasar						$ 129,264.00
7525-48	1mg	$ 370.75	$ 296.60	$ 4.15	$ 4.15	
7525-49	2mg	$ 741.50	$ 593.20	$ 7.75	$ 7.50	

Sheet1

Product		AWP	List Price	AOR Current Price	Suggested New Contract Prices	$ Volume
Zinecard						$ 372,000.00
8715-62	250 mg	$ 141.10	$ 112.88	$ 112.88	$ 95.00	
8725-89	500 mg	$ 282.19	$ 225.75	$ 225.76	$ 180.00	
Amphocin						
1045-44		$ 172.69	$ 138.15	$ -	$ 9.50	$ 998.00
Cytosar-U						$ 15,095.00
0373-01	100mg	$ 6.96	$5.57	0	$ 3.24	
0473-01	500mg	$ 92.00	$73.60	0	$ 10.35	
3295-01	1Gm	$ 52.56	$42.05	0	$ 19.71	
3296-01	2Gm	$ 102.90	$82.32	0	$ 39.41	
Depo Provera 400 mg.						$ 5,003.00
0626-01	2.5 ml	$ 96.45	$77.16	0	$ 50.36	
0626-02	10 ml	$ 366.18	$292.94	0	$ 180.68	
Zanosar						$ 35,015.00
0844-01	1Gm	$ 68.84	$55.07	0	$ 41.01	
Camptosar						
7529-01	5ml/100mg	$ 481.25	$385.00		$ 385.00	$ 10,315,174.00
Fragmin						
2406-91	2500IU/2ml	$ 139.50	$111.60		$ 95.00	
2426-91	5000IU/2ml	$ 237.13	$189.70		$ 160.00	
					Total	$ 15,793,327.00

Reading Electronic Mail

From: ROSSR Date: 09/29/95 Priority: Normal

o: 1: GAHML 4: Copy: 1: KLINKERT
2: 5: 2: THOMPSOJ
3: 6: 3: KOMENDAT

J-7

ubject: Meeting with Texas Oncology Files Attached: No

.sa, Please forward this email to Dave Marsico, Dave Westaway and Pasquale
:tera. Thanks. Randy

xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

ptember 29, 1995

Vinc. Inj $4.55
Inj $8.97 630
2mths

: Distribution
om: Randy Ross
: Meeting with Texas Oncology

met today with Bob Whren of Texas Oncology to discuss the $40 / 50
. doxorubicin price that Bristol has offered and other issues.

Informed Bob that we would keep him competitive with the
rket, however, the Rubex brand was not identical to our RDF 150.
discussed stability, sterility and single dose vial versus multi dose
al issues. There is agreement that we do have a product of more
lue to their clinic network. Agreeing on that value, and working the
ice from that point will be the next goal.

. We discussed using free goods and grants to offset some of the
ice differences as we have in the past. Bob is very open to that.

. There may be some room to bring the PFS MDV into the
icture. Bob agreed that it would be of greater significance in offices
ere RN's are doing the RDF reconstitution. Finding an premium
er the RDF will be necessary.

WE revisited the issue of capitation. The physician committees
e completing a second re-write of the treatment guidelines. Bob does
t have access to them at this time. Once completed, we can use them
decide if capitation is an option here.

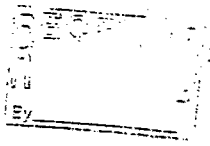
. Texas Oncology would prefer to depot their contract through
lternate Site Distributors (ASD) in Dallas. Since they do not wish to
y an up charge, the 2% would fall to us in order for this to happen. I
marked that in our efforts to respond to the Bristol pricing, we may
t be able to participate with ASD. (As mentioned before, the 2%
y be a wash for us considering the savings in shipping and invoicing
sts. I mentioned the above to Bob as an "out" if we wanted it.)

. I discussed the VP-16 pricing and upcoming request for bid.
e voluntarily lowered our contract price to the current deal. Also, I
iscussed with Bob the rapid downward market adjustment of VP-16
ince early April. He said their current supplier, Gensia, had done a
od job of keeping up with the market adjustments. He did like the
dea about linking changes in Toposar pricing to changes in the Federal
ly Schedule (FSS). When discussing how many changes have
urred in the FSS, I detected that Bob thought that possibly Gensia
id not respond as frequently or as quickly as Bob had originally
elieved.

002752

J-8

Chronicare™ exclusively from
Quantum
Health Resources



VIA FACSIMILE

March 2, 1995

David P. Mahoney
Miles, Inc.
400 Morgan Lane
West Haven, CT 06516-4175

Re: Status of Pricing Discussions Remainder of 1995

Dear Dave:

This note summarizes the results of our pricing discussions to date. These are a result of our meeting in Orange on February 15, 1995 which included yourself, Jim Patchen, John DeStefanis, and myself. Subsequent to that meeting, you and I had further telephone conversations on February 24, 1995, and March 2, 1995 which have yielded the results outlined. If you have any other understanding of these agreements you need to communicate this to me by March 7, 1995.

Agreed:

1) Koate pricing will decrease to $.17 per unit with terms of 2.5% 30, net 31.

2) Kogenate pricing will increase to $.61 per unit with terms of 2.5% 30, net 31 effective March 1, 1995. However, it is agreed that Quantum will have the opportunity to purchase 4,000,000 units of mid and high range material at $.58 per unit, even if the product does not become available until after March 1, 1995. Additional price increases of no more than $.01 on July 1 and October 1, 1995. You will endeavor to supply Quantum with 35,000,000 units of Kogenate for calendar 1995.

3) Furthermore, it is agreed that you will evaluate and determine in a timely manner a dollar amount which will offset losses in revenue and expenses outlaid in the recall of Prolastin in calendar 1994.

Miles Biologics will also support Quantum's programs that benefit the Hemophiliac population generally (such as education, camps, preceptorships, and other programs) by providing Quantum with $200,000. Quantum will be entitled to use this money to support these programs as it deems appropriate. This money will be allocated to Quantum at the rate of $50,000 quarterly.

790 The City Drive South / Suite 400 / Orange / California / 92668
(714) 750-1610 / Fax (714) 750-3235

This summarizes the full extent of the agreements we discussed. Beyond that we will negotiate a supply agreement for the balance of the year.

Regards,

Don Whiteaker
Director of Purchasing

cc: K. Coleman
J. DeStefanis
J. McIlwraith

[redacted]

J-9

Disprop. Share $48.95

FSS $44.95
whls $71.00
Distr. $51.50
AWP $109.20

Rep Min $54.00
WPO's @ $54.00
Cardinal
Bergen
AmeriNET

PHASE I

GPO

- No attempts to aggressively secure GPO awards during this period (Q1 - Q2).
- Target a total of 3 - 5 state, county or regional GPO bids to send false pricing signals to competition. Recommended pricing $53 - $58/vial.

HOSPITAL

- Concentrate field reps. on the top 40 AIDS hospitals using a $54.00 price in conjunction with a 10% free goods program to mask final price. Provides the account with an effective price of $48.60 per vial.

DISPROPORTIONATE SHARE PROGRAM

- Establish the Disproportionate Share Price at $48.50. This represents an 11% reduction to a projected AMP of $54.50/vial.
- Focus sales force on these accounts during Q1 and Q2.

What about a place like Jacobs Rx (Servers Long Term Care)

FSS

- Establish a price of $52.00/vial for Q1 and Q2.

HOMECARE/ALT.

- Focus attention of Corp. Mktng. Mgrs. on these accounts during Phase I. -- Pricing, based on current market conditions, should range from $53.00 - $61.00 per vial.
- Pricing program for Top 10 HomeCare accounts should have the flexibility to include a "Product Credit" program that guarantees long-term price competitiveness. This program would be reviewed at the end of each quarter with the account. Quarterly pricing reference would be the AMP (Average Market Price) report to HCFA plus 10%.

Example: Account buys 10,000 vials during Q2 at $57.00 per vial for a total of $570,000. At the end of Q2, an AMP is reported to HCFA of $50.00.

$50.00 X 110% = $55.00

$57.00 - $55.00 = $2.00

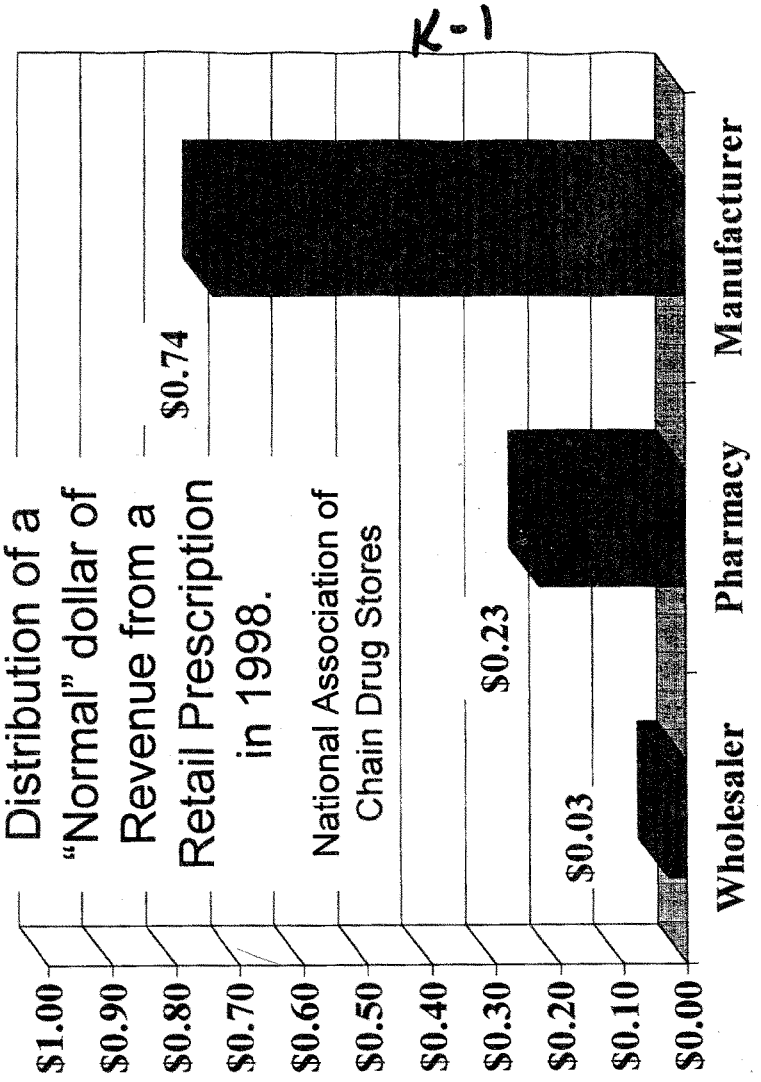
$2.00 X 10,000 = $20,000

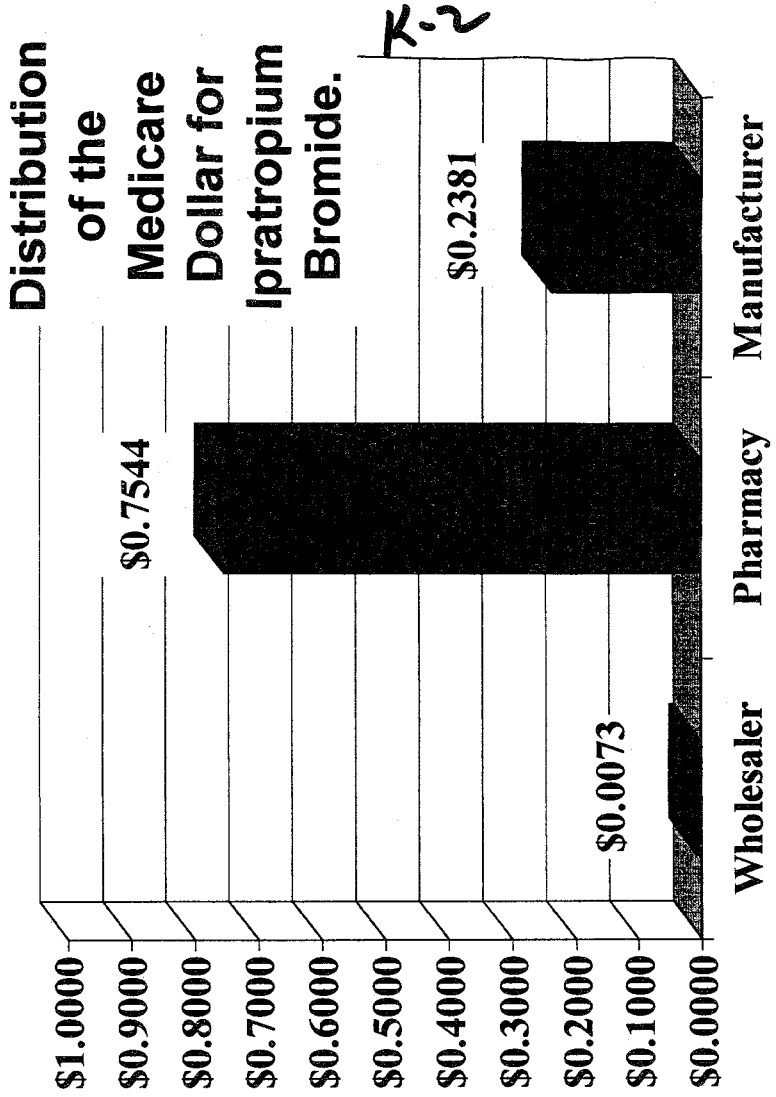
I NEED TO HANDLE
AmeriSource
Tiffin (PrimeNet)
Valley Forge, PA

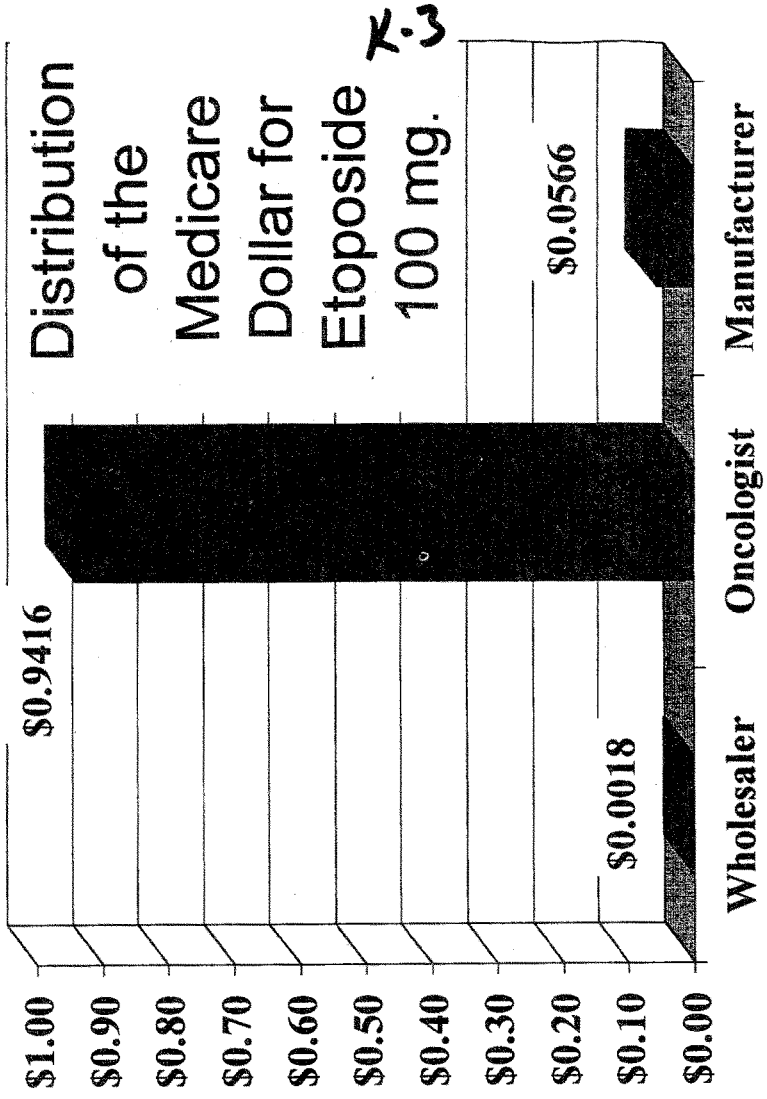
der phase

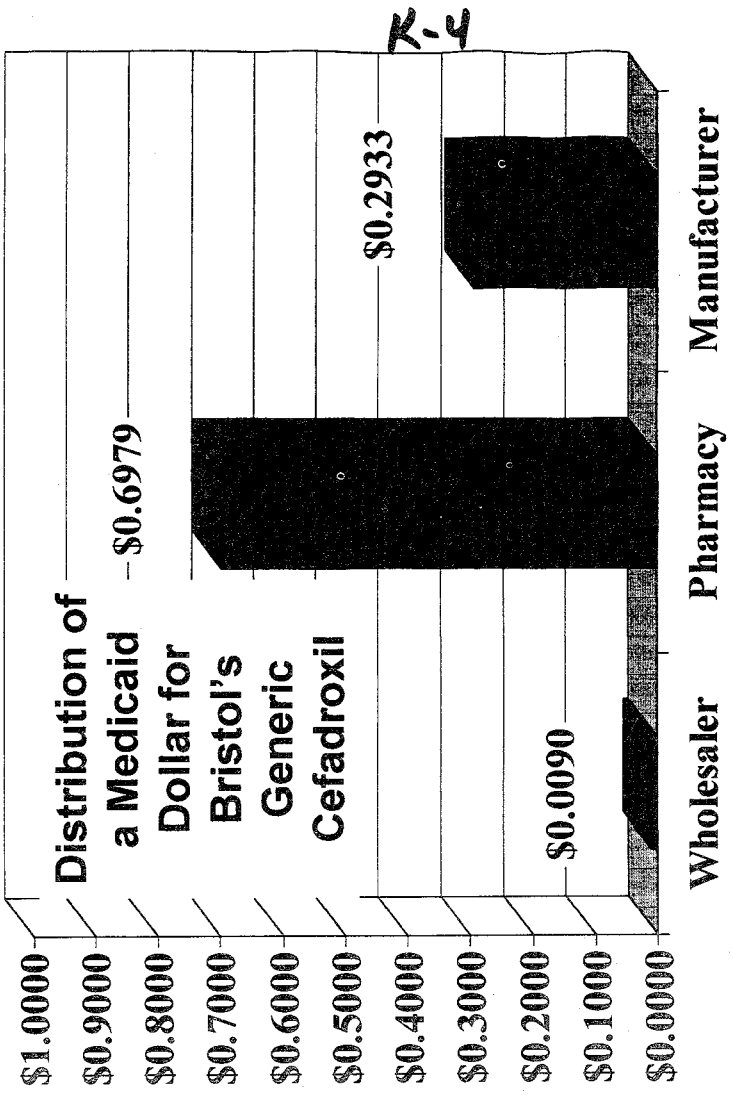
G 00888

Possible HomeCare MKT
Comm Denver
OPTIONCare Chicago
Homeko CA
NTMC Waltham Mass
Home Infu Cr Miami
Health Inf. Miami
UHC Marietta GA


K-1
Distribution of a "Normal" dollar of Revenue from a Retail Prescription in 1998.
National Association of Chain Drug Stores
$1.00
$0.90
$0.80
$0.70
$0.60
$0.50
$0.40
$0.30
$0.20
$0.10
$0.00
$0.03
$0.23
$0.74
Wholesaler
Pharmacy
Manufacturer


Distribution of the Medicare Dollar for Ipratropium Bromide.
K-2
$1.0000
$0.9000
$0.8000
$0.7000
$0.6000
$0.5000
$0.4000
$0.3000
$0.2000
$0.1000
$0.0000
$0.7544
$0.2381
$0.0073
Wholesaler
Pharmacy
Manufacturer


Distribution of the Medicare Dollar for Etoposide 100 mg.
K-3
$1.00
$0.90
$0.80
$0.70
$0.60
$0.50
$0.40
$0.30
$0.20
$0.10
$0.00
$0.9416
$0.0018
$0.0566
Wholesaler
Oncologist
Manufacturer


K-2
Distribution of a Medicaid Dollar for Bristol's Generic Cefadroxil
$1.0000
$0.9000
$0.8000
$0.7000
$0.6000
$0.5000
$0.4000
$0.3000
$0.2000
$0.1000
$0.0000
$0.6979
$0.2933
$0.0090
Wholesaler
Pharmacy
Manufacturer

CHEMO DRUGS 1995

FO OTH DR'S

CPT CODES	BRAND NAME	MCRE ALLOW	YTD 1995 VERSYS	Mth to Date YTD 1995 Medic	YTD MCRE ALLOW
J9140	DT IC 200 MG	$ 21.17	0	0	$ -
J9150	CERUBIDINE	$ 77.52	0	0	$ -
J9181	TOPOSAL	$ 14.20	1446	207	$ 23,472.60
J9182	TOPOSAL	$ 141.97	432	65	$ 70,559.09
J9185	FLUDARA 50 MG	$ 174.30	51	0	$ 8,889.30
J9190	FLURORONRACIL	$ 1.55	1930	256	$ 3,388.30
J9200	FUDR 500 MG	$ 122.94	4	0	$ 491.76
J9202	ZOLADEX 3.6 MG	$ 344.76	0	0	$ -
J9208	IFEX/FOSFAMIDE 1 GM COMBO	$ 101.94	592	51	$ 65,547.42
J9209	MESNA	$ 15.43	2125	228	$ 36,275.93
J9213	ROFERON A 3 MIL/U	$ 29.87	118	48	$ 4,958.42
J9214	INTRON A 1 MIL/U	$ 9.96	736	129	$ 8,615.40
J9217	LUPRON DEPOT 7.5 MG	$ 463.75	21	1	$ 10,202.50
J9260	METHOTREXATE 50MG	$ 4.75	242	23	$ 1,258.75
J9265	TAXOL 30 MG	$ 182.63	466	171	$ 116,335.31
J9280	MUTAMYCIN 5 MG	$ 128.95	41	2	$ 5,544.85
J9290	MUTAMYCIN 20 MG	$ 435.49	8	1	$ 3,919.41
J9293	MITOXANTRONE 5 MG	$ 154.05	35	24	$ 9,088.95
J9360	VELBAN	$ 3.75	279	49	$ 1,230.00
J9370	VINCRISTINE 1MG	$ 31.75	155	29	$ 5,842.00
Q0136	PROCRIT 1000 UNITS	$ 12.00	995	30	$ 12,300.00
Q9XX	PROCRIT 1000 UNITS	$ 12.00	588	390	$ 11,736.00
		TOTALS			$ 1,085,941.34

COST ALLOCATED BY BOOKS

$ 637,640.00

PROFIT FROM DRUGS

$ 448,301.34

F-1

CHEMO DRUGS

DECEMBER 1997

	TOTALS
MTD DRUG COST FOR DR. [redacted] AND DR. [redacted]	$ 98,945.52
% OF DR. [redacted] =MTD DRUG COST/TOTAL DRUG COST	64%
% OF DR. [redacted] =MTD DRUG COST/TOTAL DRUG COST	36%
MTD DRUG PROFIT FOR DR. [redacted] AND DR. [redacted]	$ 45,332.59
YTD DRUG COST FOR DR. [redacted] AND DR. [redacted]	$ 1,505,953.93
% OF DR. [redacted] =YTD DRUG COST/TOTAL DRUG COST	64%
% OF DR. [redacted] =YTD DRUG COST/TOTAL DRUG COST	36%
YTD DRUG PROFIT FOR DR. [redacted] AND DR. [redacted]	$ 725,178.03

000256

T-2

"A word from: Jeffrey Scott, M.D., National Medical Director, ION"

First, please let me welcome all of our members to ION! As we complete our first year as an organization, I would like to update you on our brief past, as well as our mission and plans for the coming year.

As a practicing medical oncologist in a 30-physician oncology group in Atlanta, I was more than interested, several years ago, in the possibilities offered by the emerging physician practice management (PPM) companies. Having developed a relationship with a PPM company, it was clear that some of the services they provided had merit for my practice.

ION members needn't be a PPM practice to enjoy many of the value-added services. They can be achieved simply through joining ION. Our mission is to offer a wide-ranging assortment of products and services to member physicians. How? By simply letting the practices retain 100% of their current control and autonomy, while offering those services that our membership has told us they want from ION.

ION's VALUE PRICING GROUP

Because up to 60% of our practices' profitability is derived from chemotherapy, it was logical to begin leveraging ION's considerable buying mass to negotiate better drug discounts from the pharmaceutical industry. And that is exactly what happened. Even as a very large practice, my group has experienced tremendous savings in our initial months of ION membership.

We continue to meet regularly with pharmaceutical companies on your behalf. Our model identifies underused products, and through a process of education and practice guidelines, encourages our members to increase utilization wherever reasonable. As a practicing physician, I will never choose therapy based on price alone. However, if two therapies are equivalent in efficacy, I can no longer ignore the economic differences between them. ION - through publications, practice guidelines, local & national meetings, and effective formulary management - can assist its member practices in maximizing their true potential.

L-3

L-4

Byran Manning
American Oncology Resources
lllllll
Houston, TX.

January 27,1997

Dear Bryan

We appreciate the time you and Fred Pounds extended Paula, Mike and myself last Wednesday to discuss the opportunities for partnering with AOR. We left the meeting with a further desire to continue discussions to meet your needs in developing a stronger relationship leading to a partnering position.

Below is a review of the items we discussed. Items we felt we brought to the table as a commitment to build a strong relationship and partnership with AOR.

1. A 3 year contract proposal that reduces the cost of your multi-source drugs by over $300,000.

   Some of the drugs on the multi-source list offer you saving of over 75% below list price of the drug. For a drug like Adriamycin, the reduced pricing offers AOR a reimbursement of over $8,000,000 profit when reimbursed at AWP.

The spread from acquisition cost to reimbursement on the multi-source products offered on the contract give AOR a wide margin for profit.

We will off cource give you the chance to get good price on our LHRH as soon as it is introduced, estimation is July/Agust 1997. Since we do not know your usage of this compound figure is difficult to calculate.

2. 4% Administration fee for contracted products.

   Based on the figures you shared, this would be over $128,000 to AOR in Admin fees.

3. $55,000 grant to your medical education department for a partners program.

   The grant includes sponsorship of your quarterly education meetings and the annual AOR yearbook. This amount is already committed for 1997.

4. $40,000 for the AOR monthly teleconference. This money is also already committed for 1997.

5. We have committed our Customer Development Unit to work with AOR to further develop comprehensive quality and marketing initiatives that improve the delivery of care to the patient, and provide a competitive marketplace advantage to AOR.
Support in the development of a disease management plaform of care. Each platform will cost $300,000 - $400,000. We have committed to one, but will consider additional ones as the partnership develops. The two priority areas discussed include Breast Cancer and Colon Cancer.
Providing consultation on disease management process and principles.
Comprehensive research and analysis on "Best Practices" prior to initiation of platform of care development.
Identification of quality indicators that will measure platform of care success.
Development of an organizational plan that will comprehensively assess existing resources, culture

000025

systems and processes, and make recommendations that will enhance AOR's ability to implement the platform of care.

Develop a process of change plan with AOR that implements the platform of care.

Development of customized tools and resources necessary to support implementation of the platform of care. These will include screening and risk assessment, treatment algorithms, patient education, provider education, plan marketing and promotion, and outcomes. These tools and resources will cost PNU and additional $100,000-150,000 without factoring human resource costs in.

Potential development of Internet access to this platform of care for your network, and potentially for you future customers. This will cost an additional $50,000 - $100,000 to PNU.

Close coordination with AOR's Regional Marketing Directors to enhance patient and provider recruitment opportunities as a result of disease managment development.

6.a A phase III protocol trial for "Oral Idamycin" in lymphoma. This trial will offer revenues to AOR of $1.1M (225 patients at $5,000 per patient). The patient fee can be negotiated to a performance related fee, faster arccrual equals to higher patient fee. This is a protocol study we could have placed at 2 or 3 different places. We chose AOR.

6.b The same applies to the oncotech trial, since the final protocal is not approved yet I can not specify the patients fee but it is not less than the aboved mention trial and the same performance based payment can be negotiated.

7. AOR Clinical data. We are willing to look at the clinical data offered by AOR for three for 200' there after negostiate the next coming 6 months. At the first evaluation we both may have better understanding of how our collaboration benefit both parties.

John - also consider adding the following if you choose to initiate this project.

8. We will explore the AWP-40% situation with South Carolina's BC/BS to see if we can work with an employer coalition to sensitize BC/BS to the inappropriateness of their reimbursement strategy from an employer's perspective.

The above items represent a considerable offering from PNU to the revenues, profits *and quality of care of AOR. Your greatest midterm savings to the bottom line will be by way of our short term investment of $450,000 - $650,000 in the development of a platform of care. This represents a significant partnering commitment by our company that can not be matched by any other pharmaceutical company in terms of quality and expertise. We have developed leading edge competencies in these areas that will provide a competitive advantage to our partnering customers. We do not consider this "soft" money to your bottom line; because the savings, revenue and market share you will gain are very "hard". We are enthusiastically pursuing this type of relationship, because, we believe that this is the type of collaboration that represents a true partnership that is mutually profitable, takes advantage of each of our corporate competencies, and ultimately improves the delivery of care to the patient.*

The one item not resolved is the discount on major new sole source product introductions, primarily Camptosar. The product is only in it's first 6 month of marketing. The product received accelerated approval from the FDA and was rushed to market to fill a void in colon cancer treatments. We do not know the full impact on the marketplace or the disease state yet. We feel the product has tremendous potential, but we are not at a point where we can judge the outcome of a discount to AOR. There are government pressures and prices mandated by the government for Medicaid and Federal Supply Schedules

that have not been reconciled yet. It will take some time, before we can accurately measure the effect of the drug, both economically and treatment wise to determine if discounts are a viable option at this time. Certainly, any discount we give, have an effect on our government sales, which are significant.

The Camptosar issue is not a dead issue, but one we would like a little more time to resolve.

Overall, we feel we have an offer that is fair, shows commitment to AOR on the part of PNU, and is the beginning of future, stronger relationships. You could show your interest by agreeing to the 3 year contract offered and continued negotiations of the Camptosar issue, and other issues as they develop in 1997 and beyond.

As an interim step, we are continuing our development with the Medical education and clinical research areas.

Let us hear from you.

Sincerely,

John Thompson

cc: Lloyd Everson, M.D. and any other decision makers on the clinical side whomever the acting marketing director is

A 42 year old female is diagnosed with stage 2 breast cancer confirmed after biopsy and subsequent modified radical mastectomy. The recommended protocol is "Doxorubicin and Cyclophosphamide, given together every 3 weeks for 4 treatments total. Kytril is given intravenously pre-infusion and Zofran is given intravenously post infusion to control the associated severe nausea.

2001 Breast Cancer Drug Profits Per Dose

DRUG	Ven-A-Care Cost	Medi-Cal Pays (Pharm)	Profit from Medi-Cal	Medicare Pays	Medicare Profit
Doxorubicin 84mg NDC 55390-0233-01	$47.00	$421.80	$374.80	$385.29 HCPCS J9000	$338.29
Cyclo-phosphamide 840mg NDC 00015-0539-41	$114.00	$562.42	$448.42	$562.42 HCPCS J9096	$448.42
Kytril 1mg NDC 00029-4149-01	$116.50	$185.44	$68.94	$185.44 HCPCS J1626	$68.94
Zofran 32mg NDC 00173-0442-00	$167.73	$243.58	$75.85	$194.56 HCPCS J2405	$26.83
NaCl .9% Minibag NDC 00038-0553-18	$3.06	$41.33	$38.27	$30.90 HCPCS J7040	$27.84

M-2

Total Profit on Drugs from Medi-Cal

for Total of 4 Treatments is

$4025.12

Total Profit on Drugs from Medicare

for Total of 4 Treatments is

$3641.28

(Includes 20% co-pay of $728.25)

M-3

61 year old female with stage 3 colon cancer confirmed after surgical resection of the tumor. The Oncologist's recommended protocol for subsequent treatment is :

M-4

Six Treatments of Chemotherapy with Leucovorin and Fluouracil given intravenously with Kytril to control nausea.

2001 Colon Cancer Drug Profits Per Dose

DRUG DOSE & NDC	Ven-A-Care Cost	Medi-Cal Allowed(Pharm)	Medi-Cal Profit	Medicare Allowed	Medicare Profit
Leucovorin 800mg 00641-2369-41	$80.00	$855.00	$775.00	$567.52 HCPCS J0640	$487.52
5-Fluouracil 800mg 63323-0117-10	$2.05	$5.46	$3.41	$5.04 HCPCS J9190	$2.99
Kytril 1mg 00029-4149-01	$116.50	$185.44	$68.94	$185.40 HCPCS J1626	$68.90
NaCl .9% Minibag 00038-0553-18	$3.06	$41.33	$38.27	$30.90 HCPCS J7040	$27.84

M-5

Total Profit on Drugs from Medi-Cal

for Total of 6 Treatments is

$5,313.72

Total Profit on Drugs from Medicare

for Total of 6 Treatments is

$3,523.50

(Includes 20% co-pay of $704.70)

N-1

Medicare Payments for Prescription Drugs

Response to Request from
Representative W. J. Tauzin

June 2001

OEI-03-01-00490

U.S. Department of Health and Human Services
Office of Inspector General
Office of Evaluation and Inspections

JUN 20 2001

The Honorable W. J. Tauzin
Chairman, Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Tauzin:

In response to your request, we are providing you with information on the amount of beneficiary coinsurance that would be saved if Medicare drug payments were based on prices available to other sources. In this report, we compared Medicare prices for 24 drugs to Department of Veterans Affairs prices and to wholesale catalog prices. We have enclosed four tables which illustrate the impact excessive payment amounts have on the Medicare program and its beneficiaries.

This report provides data clearly demonstrating that Medicare pays too much for prescription drugs. For example, we found that Medicare would save $1.9 billion a year if 24 drugs were reimbursed at prices available to the Department of Veterans Affairs. Over $380 million of this savings would directly impact Medicare beneficiaries in the form of reduced coinsurance payments. In some cases, the Department of Veterans Affairs price for a drug was less than the amount a Medicare beneficiary would pay in coinsurance. More conservatively, Medicare and its beneficiaries would save $887 million a year by paying the actual wholesale prices available to physicians and suppliers for these 24 drugs. Beneficiaries would pay over $175 million less in coinsurance if Medicare paid for these drugs based on catalog prices.

The majority of the data in this report was first presented in our September 2000 report, "Medicare Reimbursement of Prescription Drugs," (OEI-03-00-00310). The pricing data was collected in the second quarter of 2000 from Medicare carriers, the Department of Veterans Affairs, and several wholesale pricing catalogs. In order to provide a current estimate of potential savings, we have updated the total Medicare allowed charges data from the figures which appeared in the original report.

If you have any questions about this report, or if we can provide further assistance, please call me or George Grob, Deputy Inspector General for Evaluation and Inspections, or have your staff contact Robert Vito at (215) 861-4558.

Sincerely,

Helen Albert
Director, External Affairs

Enclosures

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TABLE 2:

MEDICARE AND THE DEPARTMENT OF VETERANS AFFAIRS
POTENTIAL MEDICARE AND BENEFICIARY SAVINGS

HCPCS CODE	GENERIC DRUG NAME	2000 MEDIAN PRICES		PERCENT SAVINGS	2000 ALLOWED CHARGES	POTENTIAL SAVINGS		
		MEDICARE	VA			MEDICARE	BENEFICIARY	TOTAL
J0640	Leucovorin Calcium, 50 mg	$18.02	$1.63	91.0%	$69,228,203	$50,372,930	$12,593,232	$62,966,162
J1260	Dolasetron Mesylate, 10 mg	$14.82	$4.95	66.6%	$82,482,309	$43,946,040	$10,986,510	$54,932,550
J1440	Filgrastim, 300 mcg	$171.38	$130.72	23.7%	$51,133,657	$9,705,191	$2,426,298	$12,131,488
J1441	Filgrastim, 480 mcg	$273.03	$208.23	23.7%	$83,837,285	$15,918,122	$3,979,531	$19,897,653
J1562	Immune Globulin, 5g	$396.63	$110.54	72.1%	$49,903,101	$28,796,164	$7,199,041	$35,995,205
J1626	Granisetron HCl, 100 mcg	$18.54	$7.81	57.9%	$42,674,561	$19,758,276	$4,939,569	$24,697,845
J2405	Ondansetron HCl, 1 mg	$6.09	$3.94	35.3%	$55,003,100	$15,534,537	$3,883,634	$19,418,172
J2430	Pamidronate Disodium, 30 mg	$243.56	$203.45	16.5%	$156,095,768	$20,564,957	$5,141,239	$25,706,197
J2820	Sargramostim, 50 mcg	$27.41	$10.06	63.3%	$27,758,142	$14,056,294	$3,514,073	$17,570,367
J7608	Acetylcysteine, per g	$5.05	$1.50	70.3%	$22,452,105	$12,626,530	$3,156,633	$15,783,163
J7619	Albuterol Sulfate, per mg	$0.47	$0.07	85.1%	$261,270,168	$177,886,072	$44,471,518	$222,357,590
J7644	Ipratropium Bromide, per mg	$3.34	$0.84	74.9%	$310,310,047	$185,814,399	$46,453,600	$232,267,999
J9000	Doxorubicin HCl, 10 mg	$42.92	$6.29	85.3%	$30,586,166	$20,882,969	$5,220,742	$26,103,711
J9045	Carboplatin, 50 mg	$101.37	$41.14	59.4%	$140,046,625	$66,568,083	$16,642,021	$83,210,104
J9170	Docetaxel, 20 mg	$283.65	$151.77	46.5%	$110,792,891	$41,209,565	$10,302,391	$51,511,957
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.86	15.4%	$100,322,242	$12,338,978	$3,084,744	$15,423,722
J9202	Goserelin Acetate, 3.6 mg	$446.49	$214.87	51.9%	$375,955,270	$156,023,668	$39,005,917	$195,029,586
J9206	Irinotecan, 20 mg	$117.81	$75.45	36.0%	$117,789,971	$33,882,239	$8,470,560	$42,352,798
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$257.00	56.6%	$633,720,145	$287,109,660	$71,777,415	$358,887,075
J9265	Paclitaxel, 30 mg	$173.49	$107.59	38.0%	$284,530,532	$86,462,906	$21,615,727	$108,078,633
J9310	Rituximab, 100 mg	$420.29	$239.58	43.0%	$135,054,269	$46,454,890	$11,613,722	$58,068,612
J9350	Topotecan, 4 mg	$573.75	$307.25	46.4%	$34,885,298	$12,963,042	$3,240,761	$16,203,803
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$46.20	38.8%	$27,866,679	$8,651,589	$2,162,897	$10,814,486
Q0136	Epoetin Alfa, per 1000 units	$11.40	$7.22	36.7%	$536,916,452	$157,495,493	$39,373,873	$196,869,366
TOTAL FOR 24 DRUGS					$3,740,614,986	$1,525,022,594	$381,255,648	$1,906,278,242

TABLE 3:

MEDICARE AND WHOLESALE CATALOGS
UNIT COSTS AND BENEFICIARY COINSURANCE

HCPCS CODE	GENERIC DRUG NAME	2000 MEDIAN PRICES		CATALOG PRICE AS PERCENTAGE OF MEDICARE PRICE	20% MEDICARE COINSURANCE	
		MEDICARE	CATALOGS		CURRENT	BASED ON CATALOG PRICE
J0640	Leucovorin Calcium, 50 mg	$18.02	$2.94	16.3%	$3.60	$0.59
J1260	Dolasetron Mesylate, 10 mg	$14.82	$8.29	55.9%	$2.96	$1.66
J1440	Filgrastim, 300 mcg	$171.38	$144.30	84.2%	$34.28	$28.86
J1441	Filgrastim, 480 mcg	$273.03	$229.90	84.2%	$54.61	$45.98
J1562	Immune Globulin, 5g	$396.63	$300.00	75.6%	$79.33	$60.00
J1626	Granisetron HCl, 100 mcg	$18.54	$13.81	74.5%	$3.71	$2.76
J2405	Ondansetron HCl, 1 mg	$6.09	$5.49	90.1%	$1.22	$1.10
J2430	Pamidronate Disodium, 30	$243.56	$223.26	91.7%	$48.71	$44.65
J2820	Sargramostim, 50 mcg	$27.41	$23.13	84.4%	$5.48	$4.63
J7608	Acetylcysteine, per g	$5.05	$3.38	66.9%	$1.01	$0.68
J7619	Albuterol Sulfate, per mg	$0.47	$0.13	27.7%	$0.09	$0.03
J7644	Ipratropium Bromide, per mg	$3.34	$1.53	45.8%	$0.67	$0.31
J9000	Doxorubicin HCl, 10 mg	$42.92	$10.08	23.5%	$8.58	$2.02
J9045	Carboplatin, 50 mg	$101.37	$87.79	86.6%	$20.27	$17.56
J9170	Docetaxel, 20 mg	$283.65	$238.86	84.2%	$56.73	$47.77
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.49	84.2%	$17.69	$14.90
J9202	Goserelin Acetate, 3.6 mg	$446.49	$375.99	84.2%	$89.30	$75.20
J9206	Irinotecan, 20 mg	$117.81	$98.63	83.7%	$23.56	$19.73
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$499.03	84.2%	$118.52	$99.81
J9265	Paclitaxel, 30 mg	$173.49	$146.10	84.2%	$34.70	$29.22
J9310	Rituximab, 100 mg	$420.29	$353.93	84.2%	$84.06	$70.79
J9350	Topotecan, 4 mg	$573.75	$507.32	88.4%	$114.75	$101.46
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$64.11	84.9%	$15.10	$12.82
Q0136	Epoetin Alfa, per 1000 units	$11.40	$10.72	94.0%	$2.28	$2.14

TABLE 4:

MEDICARE AND WHOLESALE CATALOGS:
POTENTIAL MEDICARE AND BENEFICIARY SAVINGS

HCPCS CODE	GENERIC DRUG NAME	2008 MEDIAN PRICES		PERCENT SAVINGS	2008 ALLOWED CHARGES	POTENTIAL SAVINGS		
		MEDICARE	CATALOGS			MEDICARE	BENEFICIARY	TOTAL
J0640	Leucovorin Calcium, 50 mg	$18.02	$2.94	83.7%	$69,228,203	$46,346,784	$11,586,696	$57,933,480
J1260	Dolasetron Mesylate, 10 mg	$14.82	$8.29	44.1%	$82,482,309	$29,074,736	$7,268,684	$36,343,420
J1440	Filgrastim, 300 mcg	$171.38	$144.30	15.8%	$51,133,657	$6,463,762	$1,615,941	$8,079,703
J1441	Filgrastim, 480 mcg	$273.03	$229.90	15.8%	$83,837,285	$10,594,886	$2,648,721	$13,243,607
J1562	Immune Globulin, 5g	$396.63	$300.00	24.4%	$49,983,101	$9,726,217	$2,431,554	$12,157,771
J1626	Granisetron HCl, 100 mcg	$18.54	$13.81	25.5%	$42,674,561	$8,709,846	$2,177,461	$10,887,307
J2405	Ondansetron HCl, 1 mg	$6.09	$5.49	9.9%	$55,003,100	$4,335,220	$1,083,805	$5,419,025
J2430	Pamidronate Disodium, 30 mg	$243.56	$223.26	8.3%	$156,095,768	$10,408,094	$2,602,023	$13,010,117
J2820	Sargramostim, 50 mcg	$27.41	$23.13	15.6%	$27,758,142	$3,467,489	$866,872	$4,334,361
J7608	Acetylcysteine, per g	$5.05	$3.38	33.1%	$22,452,105	$5,939,804	$1,484,951	$7,424,756
J7619	Albuterol Sulfate, per mg	$0.47	$0.13	72.3%	$261,270,168	$151,203,161	$37,800,790	$189,003,951
J7644	Ipratropium Bromide, per mg	$3.34	$1.53	54.2%	$310,310,047	$134,529,625	$33,632,406	$168,162,031
J9000	Doxorubicin HCl, 10 mg	$42.92	$10.08	76.5%	$30,586,166	$18,722,268	$4,680,567	$23,402,835
J9045	Carboplatin, 50 mg	$101.37	$87.79	13.4%	$140,046,625	$15,009,041	$3,752,260	$18,761,302
J9170	Docetaxel, 20 mg	$283.65	$238.86	15.8%	$110,792,891	$13,995,878	$3,498,970	$17,494,848
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.49	15.8%	$100,322,242	$12,674,671	$3,168,668	$15,843,338
J9202	Goserelin Acetate, 3.6 mg	$446.49	$375.99	15.8%	$375,955,270	$47,490,150	$11,872,538	$59,362,688
J9206	Irinotecan, 20 mg	$117.81	$98.63	16.3%	$117,789,971	$15,341,391	$3,835,348	$19,176,739
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$499.03	15.8%	$633,720,145	$80,050,211	$20,012,553	$100,062,764
J9265	Paclitaxel, 30 mg	$173.49	$146.10	15.8%	$284,530,532	$35,936,556	$8,984,139	$44,920,694
J9310	Rituximab, 100 mg	$420.29	$353.93	15.8%	$135,054,269	$17,059,081	$4,264,770	$21,323,851
J9350	Topotecan, 4 mg	$573.75	$507.32	11.6%	$34,885,298	$3,231,275	$807,819	$4,039,094
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$64.11	15.1%	$27,866,679	$3,363,194	$840,799	$4,203,993
Q0136	Epoetin Alfa, per 1000 units	$11.40	$10.72	6.0%	$536,916,452	$25,621,276	$6,405,319	$32,026,595
TOTAL FOR 24 DRUGS					$3,748,614,986	$709,294,617	$177,323,654	$886,618,271

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taking advantage of TAP's quantity discount program Zeneca has a simular quantity discount program

To increase physicians' return to practice, TAP can either raise the price of Lupron Depot or increase the quantity discount percentages

The pricing decision for the 3 month depot, and now the four month depot, was based on the need to have reimbursement maintained for the offices converting to the three and four month

REDACTED

Utilizing this coding will has been and will continue to be beneficial for urology offices because

- Most offices now file Medicare claims electronically. The current J9217 Lupron Depot code can be used with a "3" or "4" in the units column. If TAP would have changed the pricing structure, we would have to use a miscellaneous code of J9999 (otherwise unclassified anti-neoplastic agent) requiring a manual review of claims.
- They will not have to submit invoices on what was paid, which is required when a J9999 is used.
- The four-month launch in the physician market should be timed to coincide with the price increase on July 1, 1997.

Is this a billing issue?

Since TAP did not have a price increase for the three month, the pricing of Lupron Depot 30 mg at four times the price of Lupron 7.5 mg will be positively perceived by customers. For those customers who felt TAP should have lowered our price, it will be explained that pricing and reimbursement (and therefore RTP) are linked and it is necessary to keep pricing parity between the one-month and three-month products

Launch Strategy
Lupron Depot-4 Month 30 mg should be offered to all customers. The four month depot differentiates the Lupron product line even further from current or anticipated competition.

The promotional message for the four month is that Lupron Depot - 4 Month 30 mg is more convenient for both the physician practice (fewer patient visits allows more time for other procedures and more administration time) and the patient (3 visits to the office vs 4 or 12 over the course of a year). While Lupron Depot 30 mg will cannibalize the one and the three month, opportunities now exist to capture the orchiectomy market and eliminate Zoladex 10.8 mg competition due to the added convenience of the four month. With fewer office visits, the practice reduces costs relative to time spent with patients and administration (billing). Private practice physicians will have time to perform other procedures. There will also be reduced costs to Medicare and managed care with the reduction in office visits

Private Practice Market

The list price for Lupron Depot-4 Month 30 mg would be established at four times the price of Lupron Depot 7.5 mg. AWP will also be established at four times its current Lupron Depot 7.5 mg level. Currently, 60% of the private practice market has converted to three month. Based on feedback from TAP's largest volume urology practices, the three month Lupron Depot is the preferred duration of depot, even if there were a four or six month product available. There have only been a handful of urologists who would prefer a four month product.

The quantity discount program should remain similar to the current program. It should just incorporate Lupron Depot 30 mg as an equal contributor to quantity discount tiers. An example (using 3/97 pricing) is shown below.

Lupron Depot-4 Month 30 mg Pricing Structure

Units	AWP	Cost	Discount	RTP
1-2	$2,062.50	$1650.00	0%	$412.50
3-5	$2,062.50	$1,600.50	3%	$462.00
6-11	$2,062.50	$1,567.50	5%	$495.00
12-14	$2,062.50	$1,534.50	7%	$528.00
15-17	$2,062.50	$1,501.50	9%	$561.00
18-25	$2,062.50	$1,468.50	11%	$594.00

Since it is unrealistic for an account to order all Lupron Depot 30 mg, a blended discount schedule for all three products will be developed. Note that this chart takes into account only customers purchasing at the non-contracted pricing. Contracted customers would receive even steeper discounts.

Fill - Per Feb 97 Health Policy Brief, keeps office visit from to 50 yr

For those private practice customers who feel they will be losing office revenue due to billing for fewer office visits, it is important to emphasize that there will now be time to see additional patients. In addition, Medicare will be paying for the four month within the same time frame as the one month allowing investment opportunities for payment collected sooner.

If it becomes necessary to further differentiate the Lupron product line from its competitors, we could offer deeper discounts in the quantity discount program for Lupron Depot 30 mg. This would make it more attractive to private physicians to switch from 3 month to 4 month.

Cost Sensitive Markets

It then makes sense to offer a price to cost sensitive markets which would be, for example, "four months for the price of three." With the competition increasing based on the prices Zeneca is offering for Zoladex in some cost sensitive markets, it makes sense for TAP to become more competitive in these markets with pricing for Lupron Depot. A recent example of Lupron market share loss to Zoladex is in the government Veterans Administration system. The price which Zeneca offered for Zoladex 3.6 mg was $131 compared to our offering of $273 for Lupron Depot 7.5 mg. $273 is 35% below list price for Lupron Depot 7.5 mg.

Another competitive situation which is likely in the fourth quarter of 1997 is the launch of Upjohn's GnRH analog, Decapeptyl. While Decapeptyl will only be available in a one-month

formulation, the administration of the product is identical to Lupron Depot, so there are no perceived advantages for Lupron. It is anticipated that Upjohn will have a lower price than Lupron, and perhaps Zoladex, when they enter the market so that market share can be gained.

There is a unique opportunity for TAP in these cost sensitive markets with Lupron Depot 30 mg's use for the treatment of prostate cancer. Currently, the trend has been to evaluate patients on a quarterly basis. The main evaluation method for prostate cancer patients has been the PSA. By changing a patient's visit to every four months, reduced overall costs for the organization can be shown since the patient's evaluation period would also be altered.

The current utilization for three month in the cost sensitive markets needs to be determined. The shift from one to three month is not happening as quickly in hospitals, government institutions, and managed care organizations as it has in the private practice market. It could be that the formulary approval process just takes longer when there are more decision makers. There needs to be an effort to determine if there are underlying reasons why we may not be seeing the shift to 60% use of three month in the aforementioned markets. An example of why we might not see this shift comes from the managed care market. Managed care organizations may be concerned about a high percent disenrollment rate and may hold back on using the longer Lupron depot formulations. Even a quick survey of key institutions utilizing the specialty salesforces for administration could uncover any reasons for lack of three or four month acceptance.

For accounts not able to capitalize on "return to practice," such as managed care and hospitals, there will be a positive perception of the product due to a 33% reduction in office visits per year (four instead of 12). These accounts have contracted prices with TAP based on the one month pricing of the product.

Other Considerations

With a May 30 approval, TAP could start taking orders for Lupron Depot 30 mg in private practice accounts in June, even though product may not be available until early July. It will be important to determine as soon as possible in which markets the Lupron Depot-4 Month product will be launched so that Takeda can be advised on 1, 3, and 4 month product distribution.

Since there are a number of managed care organizations, hospitals, and government accounts that purchase Lupron through a wholesaler, the drug needs to be placed into the wholesale system.

Launch Materials

The following materials will be required if there is a roll-out which is similar to the launch of Lupron Depot-3 Month 22.5 mg.

Salesforce Training Program

The Lupron salesforce should receive a training program by June 1997 if the launch is July 1, 1997. There should be a publication of the clinical data by that time for representative review. The training program will focus on the efficacy and safety profile and the number of days that an injection could be delayed.

Physician Announcement Letter

Joe [illegible]
Never mind, although maybe you may want to mail it at the bottom of this page

This letter will announce the approval of Lupron Depot 30 mg. All urologists on TAP's Epsilon mailing list will receive a letter that will ask the urologists to call their TAP representative to learn more about availability.

What about letter to wholesalers?

Physician Information Folder

At July district sales meetings, reps will receive the necessary launch materials. These materials include:

- **Product Profile*** with clinical results stating consistent leuprolide levels over four months and castrate testosterone levels for four months. The safety of the product will also be discussed.
- **Patient Conversion Worksheets*** for having offices inventory their current patients on an GnRH analog: 1. Ask those patients if they want to change to the four month product as they come in throughout the month; 2. Place a 4 Month sticker on the charts of those patients wishing to convert. This conversion process helps both TAP and the account. Since TAP may not be able to supply drug until sometime in the third quarter, this gives the office the opportunity to determine which patients may stay on the one or three month.
- **Reimbursement Instructions** asking offices to bill using the Lupron Depot 7.5 code, J9217, x 4 units.
- **Pricing Information** providing a list price of $1650. TAP keeps the same 90 day payment terms. This is done to instill confidence in accounts that the timeframe for Medicare reimbursement is expected to be the same, within 45 days. The quantity discount pricing is not officially published, but is presented by the representative since converting to one month units can be confusing.

Announcement Letter to Payers*

This letter announces the approval of Lupron Depot 30 mg, the list price and the AWP, and the recommended use of J9217 x four units. This letter will go to all Medicare and Medicaid carriers and all private insurers including managed care organizations.

Medigap Assistance Program

This program was introduced in late 1995 to help patients without a Medigap plan. The program assists patients in finding coverage for the 20% out-of-pocket costs for "Part B" services, including Lupron. Since the 20% co-pay is over $300 for the four month, the importance of reps continuing to utilize this program increases. This becomes particularly important if HCFA changes reimbursement to acquisition cost of medications.

Cash Flow Analysis Computer Program

This program helps evaluate pricing, cash outlay, and "return to practice" for combination Lupron one, three and four month orders in comparison to Zoladex one and three-month orders. Upjohn's product, Decapeptyl, may be added to this program. This program is meant to avoid customer confusion because different strategic directions were taken between TAP and Zeneca in the pricing of the three month products. An important addition is the incorporation of the time value of money and the additional "return to practice" generated by collection of the entire four months of Lupron within the same timeframe that one and three month is also collected.

Patient Information*

Patients will receive information that helps to answer most questions they may have about the four month.

Sales Aid*
Representatives will have a sales aid to work with. After the initial sales aid, product information will be incorporated into ongoing promotional pieces and programs such as "Profiles of Decision."

LEP Programs/Regional Programs/Slide sets*
For any programs held in 1997 close to the approval of Lupron Depot 30 mg, the selling message for the four month will be incorporated into programs.

Market Research*
Market research will be ongoing for the four month throughout the launch and questions will be incorporated into the primary research wave mailings which have been ongoing with urologists since 1991.

Individual phone interviews: 30 urologists will be contacted by phone and asked questions about

- The number of prostate cancer patients treated with GnRH analogs and the percentage of Lupron vs. Zoladex used
- The messages received from the TAP and Zeneca sales representatives about the four month depot
- The perceived product differences between Lupron 30 mg and Zoladex 10.8 mg
- The perceived differences in pricing between the one, three, and four month products
- The perceived differences in cash outlay vs. "return to practice" between the one, three, and four-month products
- The perceived differences between reimbursement for the products available

COMdat: This secondary market research effort will give us the main message that urologists are hearing when a TAP representative and a Zeneca representative talk to them. There will be a minimum of 20 urologists giving specific messages they heard during a sales call.

Wave Tracking Surveys : This mail survey, which has been ongoing since 1991, will continue to be done quarterly. There are two surveys. One contains questions for urologists about prostate cancer disease and its treatment, while the other survey contains questions about the products used to treat prostate cancer. The disease survey goes out in quarters one and three. The product surveys are mailed in quarters two and four. The product survey in the fourth quarter will go out after launch so that we can get responses from urologists after initial use of Lupron Depot 30 mg.

IDIs : In-depth interviews with urologists and oncologists will be scheduled as needed if TAP needs urology assistance in competitive, pricing, or reimbursement issues which may unexpectedly arise or if we need assistance in strategy direction. IDIs will be conducted in late 1997 to determine the anticipated conversion of three month to four month use in 1998.

"TAP Into the Future" Consultant Meetings : There are three consultant meetings scheduled so that Marketing will have one-on-one contact with 150 "large volume" customers. This contact

will allow us to discuss four month strategies, the feasibility of the developing LDS (Lupron Distribution System), and potential new urology products (PDS, Lupron Depot 45 mg, apomorphine, and TNP-470)

*=Would be utilized if reimbursement were either fee for service or acquisition

Product Differences
TAP will be able to continue to differentiate more strongly between the four-month and three-month products, particularly in the area of administration. The biggest difference is that Zoladex three-month is administered with a 14 gauge needle and Lupron Depot-4 and 3 month is administered with a 22 gauge needle. A 14 gauge needle may cause some issues to be raised

- Local anesthetic should be considered and this takes additional time when giving injections
- Who is qualified to give a 14 gauge injection? In most cases, it will be the physician. Nurses reluctance to use a 16 gauge needle when administering the Zoladex one-month has kept the product out of offices.
- When an injection is given, there is a need to aspirate for blood return into the syringe. This cannot be done with the Zoladex syringe
- Vessel puncture and large bone precautions need to be taken.

TAP will have a more user-friendly product and we will continue to capitalize on this.

Ongoing Clinical Studies
Zeneca initiated a US study at 10 institutions targeting 100 patients in 1996. It is a two year study for patients with advanced disease requiring one year of treatment (4 injections, 1 every 13 weeks) and one year of follow-up. The investigator meeting was held in April, 1995, but there were still protocol revisions being made in July. Dr. Michael Sarosdy from the University of Texas Health Sciences Center is the lead investigator for the study. TAP has talked with several investigators about the study and they were told by Zeneca that this is a marketing study. Zeneca did file their original NDA with only European data from the Netherlands. The study may have been initiated for several reasons:

- The study could be a Phase IV requested by the FDA to provide US clinical information
- The study could be a dosing study to change the current labeling to thirteen weeks or 91 days.

There has been no recent information on Zeneca conducting any studies for a six month depot.

Tap 4 month study ready for release?

0-2

SB

SmithKline Beecham

Pharmaceuticals

MEMORANDUM

Marketing Research

Solutions through commitment — committed to customers, committed to team, committed to excellence.

6 August, 1996

MEMO TO: Ursula Bartels
Ashok Chainani

cc: B. Carter
A. McClafferty
D. Pemock
B. Rosen
D. Tassé
R. Van Thiel

FROM: Louis Deppe

SUBJECT: Zofran Downdosing and Pre-Mix Bag Sales

In an effort to slow the downdosing of Zofran IV by physicians and to stop the rapidly deteriorating Zofran multidose vial sales, Glaxo launched a 32 mg pre-mix minibag in April of 1995. As one can see (Attachment A, graph 1), this strategy has been somewhat successful with regard to downdosing. Indeed, the average daily dose of Zofran was precipitously declining and, at one point (March 1995), reached a low of 23.7 mg per day across all emetogenicities. This trend continued until the pre-mix bag was introduced in April 1995. Since that time, the average daily dose has slowly increased and has since stabilized at around 26 mg per day.

As far as stopping the Zofran IV decline in market share and sales, this strategy has, at best, slowed the deterioration. Although the pre-mix bags have been somewhat successful in capturing market share and sales dollars, it has largely been at the expense of the Zofran multidose vial, as total Zofran IV sales continue to decline across all channels (Attachment A, graph 2 & 3). The only exception is in the clinic setting where total Zofran IV sales (multidose vial plus pre-mix bag) are relatively stable at around $7.8 million per month (Attachment A, graph 4).

1

Interestingly, Zofran IV sales in hospitals has continued to decline despite the introduction of the premix bag. In fact, the premix bag only represents 10.5% of Zofran IV sales in hospitals as compared to over 36% of Zofran clinic business. The reason for the lack of the premix bag sales in the in-patient hospital setting is that the cost of using IV Zofran is covered by DRGs, hence, the financial incentive based on 3rd party reimbursement, especially Medicare, does not exist. Thus, the decision in a hospital setting is to use the lowest cost treatment in an attempt to come in under the fixed capitated payment, which would support down dosing Zofran IV from a multidose vial.

In the clinic setting however, since Medicare reimbursement is based on AWP, product selection is largely based upon the spread between acquisition cost and AWP. For example, the average daily dose of Zofran IV in the clinic setting is 26 mg. The average cost of Zofran (taken for a multidose vial) to a clinic purchased through an oncology supply house is $4.18 per milligram or $108.60 for the 26 mgs. The AWP (also the amount reimbursed by Medicare) is $6.11 per milligram or $158.87 for the 26 mgs. Therefore, the spread between the AWP and clinic cost represents a profit to the clinic of $50.27 for the medication alone. When the Zofran 32 milligram pre-mix bag is considered, the cost to a clinic is $123.47 when purchase through an oncology supply house. Since the AWP is $195.54 for the 32 milligram pre-mix bag, this represents a spread or profit of $70.07, almost $20 more for the pre-mix bag. Further, this is costing the Medicare system an additional $36.67 ($195.54 minus $158.87) each time the Zofran 32 mg pre-mix bag is used in clinics versus using 26 milligrams for a multidose vial. (Please note the Zofran Ad within Attachment B that appeared in the Oncology Therapeutics Network (OTN)[1] November/December sales catalog. In this ad, Glaxo acknowledges the fact that downdosing exists and that one would receive less profit by using a 24 mg dose from the vial than by using the full 32 mg dose, either from a vial or premix bag).

As of late, Glaxo promotional efforts have focused almost entirely on the financial benefits of "up-dosing" rather than the efficacy of Zofran. Though physicians have certainly benefited financially from such tactics, it is costing 3rd party payers and patients more for medication. I have attached three recent promotional examples that support this. As mentioned earlier, Attachment B contains an ad that appeared in the OTN November/December sales catalog. This ad clearly demonstrates to the buyer that the profit per patient (mislabeled as reimbursement per patient) for 32 milligrams of Zofran from the premix bag is substantially higher ($67.11) than 32 milligrams from their multidose vial (MDV) ($52.06) or 1 milligram of *Kytril* ($38.00). (By the way, the *Kytril* amount was understated and they have since dropped it from their ad). Attachment C is a similar ad that ran in OTN's May/June catalog which demonstrates the same point in a slightly different fashion and minus the *Kytril* comparison. Attachment D was discovered circulating in the field by one of our oncology reps. This piece, crafted with care by a resourceful Glaxo representative[2] and made to look like an authentic Oncology Therapeutics Network ad, also demonstrates to customers the profit gained by "up-dosing" Zofran.

From this analysis, there seems to be no other reason, other than profitability, to explain uptake differentials between the hospital and clinic settings, therefore explaining why physicians are willing to use more expensive drug regimens.

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[1] Oncology Therapeutics Network is a major distributor of oncologic pharmaceuticals to hospitals and clinics.
[2] Oncology Therapeutics Network has verified with SB that although this looks very similar to one of their ads, it was not produced by them.

0-3

Toby Hartnoll
12/07/98 02:51 PM

To: Practice Managers, Physician Advisory Board, Mark Kansmuri, Grant Swanson/Oncare @ Exchange, Jonathon Cho/Oncare, Carl Higuchi/Oncare, Leeann Peng, Margaret Sunderland/TX00/Oncare, Gregory Friese/TX00/Oncare @ Exchange, Miguel Mir-Quesada/TX00/Oncare, Sandi Olsen/TX00/Oncare, Ajit Deva/TX00/Oncare, Kenneth Deaton/Southeast/Oncare, Michael Shaer/Southeast/Oncare @ Exchange, Ravi Sarma/Southeast/Oncare, Rita Farwell/Southeast/Oncare, Cathy Pyritick/Southeast/Oncare, Tom Barrett/Southeast/Oncare @ Exchange
cc: Kim Bergstrom/Oncare, Kevin Redondi/Oncare @ Exchange, John Kennedy/Oncare @ Exchange, Rick Hilpert/TX00/Oncare @ Exchange, Michael Goldberg/Oncare, Louis Stripling/GA00/Oncare
Subject: Anti-Emetic Contract for 1999.

To: Medical Policy Committees, Physician Advisory Committee, Practice Managers:

A year ago, the OnCare Medical Policy Committees and the Physicians Advisory Committee approved a therapeutic interchange program for anti-emetics, declaring that we consider the 5HT3 products to be equivalent. Subsequently we signed a very favorable purchasing agreement with SmithKline Beecham, the makers of Kytril. During this contract year, we achieved approximately 85% compliance with the program, resulting in significant savings by the practices that participated. The current contract ends 12/31/98, and I have been involved in negotiations with the three companies that have 5HT3 anti-emetic products (Anzemet by Hoechst Marion Roussel, Kytril by SmithKline Beecham, and Zofran by Glaxo Wellcome). The results can be summerized as follows:

Name	Typical dose	Cost/dose	AWP/dose**	Margin
Anzemet	100mg	$81.25	$149.88	$68.63
Kytril	0.7mg	$84.40	$130.20***	$65.80
Zofran	20mg	$83.50	$122.20	$38.70
Zofran Bag*	32mg	$105.28	$195.52	$90.24

In addition to the above prices, both SKB and HMR have committed to contribute to research and educational programs through the OnCare Foundation. If Anzemet is selected, HMR will sponsor at least two nursing programs to deal with conversion issues. All three have committed to provide an adequate amount of oral products at no cost for indigent patients. Also, HMR has a program through OTN whereby they will provide up to $300 a month toward the Lynx station lease in return for utilization data. It will be up to each practice to decide if they want to participate in the Lynx program.

Recommendation:

I recommend that we switch to Anzemet as our preferred anti-emetic because of demonstrated efficacy and economic advantages to each practice. The margin is much greater than the other products. It has been on the market for over a year and a number of you have tried the product and found it to be effective. As of 1/1/99 there will be a J code, facilitating reimbursement. The advantage company- wide will be over $800,000. We need to make a decision ASAP. If I have not heard from you by Friday Dec 11, I will assume that you are supportive of this switch.

I appreciate your commitment to this program and to making it successful. Our ability to get good pricing depends on our ability to generate market share for selected products.

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* I don't consider the Zofran prefilled bag to be a comparable product, since it results in a much higher dose than required for therapeutic effect (with a much higher probability of side effects such as headaches). It is also not consistent with the OnCare treatment guidelines.

** I am using AWP for comparison purposes only, realizing that Medicare pays less and other payers may pay more.

0-4

Attention	Mrs Debbie Laird RPh	Date	5/28/98
Company	SmithKline Beecham Oncology	Number of Pages	1
Fax Number	15137338061		
Voice Number	River Valley Reg Office		

From:	Anthony W Godar R Ph
Company	SmithKline Beecham Oncology
Fax Number	618-376-2709
Voice Number	618-376-2709

Subject: Anzimet Cost Comparison

Comments

H: Debbie.

Here is a cost comparsion high-lighting the medicare spread differences between Zofran, Anzimet, and Kytril being distributed by Steve Jeworski of HMR in Barnes Hospital / Washington Univ. Medical Ctr. This sheet was supplied to me by the reimbursement person for Barnard Cancer Ctr. yesterday; she had received it aprox. 10 days ago.

Tony Godar

Anzemet Injectable

The first true once daily IV and oral 5HT3

Item	Price	AWP	Spread
100 mg IV in 5 ml vial	**$70.00**	149.88	**$79.88**

Zofran Injectable

Item	Price	AWP	Spread	Diff
Zofran 40 mg vial	$165.00	$244.43*	N/A	
@ 32 mg use	**$132.00**	**$195.54**	**$63.54**	**$16.34**
@ 24 mg use	$99.00	$146.66	$47.66	$32.22
@23.60 mg use	**$97.35**	**$144.21**	**$46.86**	**$33.02**
@20 mg use	$82.50	$122.23	$39.73	$40.15
@16 mg use	$66.00	$97.77	$31.77	$48.11

Kytril Injectable

Item	Price	AWP	Spread	Diff
Kytril 1 mg vial	**$125.90**	$177.40	**$51.50**	**$28.38**
@ .94577 use	$119.07	$167.78	$48.71	$31.17
@ .7 mg use	$87.50	$124.18	$36.68	$43.30

- Anzemet has a $16.34 spread difference versus 32 mg Zofran; and a $40.15 spread difference versus 20 mg Zofran. **A practice doing 20 treatments per day, 100 treatments per week would receive between $84,968.00 (all use at 32 mg) and $208,780.00 (all use at 16 mg) additional income per year by switching to Anzemet.** 1997 IMS data shows TOTAL average office use per IV treatment is 23.6 mg. At this AVERAGE use, Anzemet will increase reimbursement to the practice by $171,704.00.
- **All this while saving the patient almost 47% versus 32 mg Zofran.**

- Anzemet has a $28.38 spread difference versus 1 mg Kytril and a $43.20 spread difference versus .7 mg Kytril. **A practice seeing 100 patients per week would receive between $147,576.00 (all use at 1 mg) and $224,640.00 (all use at 0.7 mg) additional income per year while saving the patient almost 45% versus 1 mg Kytril.** 1997 IMS data shows TOTAL average office use per IV treatment is .94577 mg. At this AVERAGE use, Anzemet will increase reimbursement to the practice by $162,084.00.

- A practice will tie up between 45-47% less money in 5HT3 inventory during any given month simply by switching to Anzemet.

NOTE: All Prices quoted are current as of May 3, 1998.

0-5

March 2, 1994

Dear Contracts Administrator:

GeriMed

Please accept the following bid package as a formal request for quotation to GeriMed. GeriMed is a group purchasing organization designed for "closed door" pharmacies servicing the long term care institutionalized patient. I request that you read all materials enclosed carefully before pricing your products for GeriMed especially the GeriMed history and corporate goals.

Please find enclosed the following information: 1) history and corporate goals 2) incentive or performance contract criteria 3) GeriMed membership criteria 4) instructions for submission of quotes 5) a 3.5 inch disk with instructions 6) "Request for Quotation" document 7) a new agreement that must be executed with the bid and 8) a participating wholesaler list as of March 1, 1994.

1707 Shelbyville Road
ouisville, Kentucky 40223
02-423-0351
02-339-1417 FAX

Information regarding this bid proposal is also being sent to your national accounts or sales personnel for their information. Bids are due at close of business on March 28, 1994. If this date does not give you enough time to complete the bid document please call our office immediately. We anticipate awards being made near the end of May. Preference will be given to two year agreements.

Thank you for your time and expertise on this bid. GeriMed looks forward to continuing or beginning our relationship during the next year.

Sincerely,

Susan M. Rhodus, R.Ph.
Vice-President of Operations

Enclosures

GeriMed Request for Quote Instructions

BASIC INFORMATION

Name of Group:	GeriMed, Inc.
Address:	9707 Shelbyville Road
City, State, Zip:	Louisville, KY 40223
Phone:	(502) 423-0351
Fax Number:	(502) 339-1417
Type of Group:	Group purchasing organization for "closed door" long term care pharmacies (no retail activity) See membership criteria attached.
Membership: (as of March 1, 1994)	489,000 beds serviced by 380 pharmacies in 41 states
Contract contacts:	Susan M. Rhodus, R.Ph., Vice President of Operations Angela Meiners, Contracts Administrator Kim Wissing, R.Ph., Contracts Analyst
Membership contact:	Robert Benim, Director of Membership Services
Rebates/Data Collection:	Patrick Curran, Usage Analyst

REQUIREMENTS FOR SUBMISSION OF REQUEST FOR QUOTES

1. Bids must arrive at our offices no later than close of business March 28, 1994. They should be returned to:
   Susan M. Rhodus, R.Ph.
   Vice President of Operations
   GeriMed
   9707 Shelbyville Road
   Louisville, KY 40223

2. Bids must include the following minimum information to be placed under consideration for review. Bids without the enclosed information will result in the return of the bid package for completion.

   A. **First two pages of the "Request for Quote" document completed along with any addendum attached.** The first two pages must be completed to have the bid accepted by GeriMed. Manufacturers and suppliers with previous contracts through GeriMed will find the first page printed out with our most up to date information. **Please review this material for accuracy to ensure efficient administration of the contract.** The second sheet must be signed by an authorized representative of the company. This signature represents a legal offer being made to GeriMed with terms and conditions and prices to be held firm for the term of the offer. Please attach any additional comments, requirements, and restrictions to the second page.

B. Both copies of the supplier agreement signed with any exceptions or addendum attached.
GeriMed will execute both agreements when awards are made and return one copy to your offices along with a complete, current membership list. Please initial any changes made in the agreement and attach any additional pages to each contract.

C. Completed 'Request for Quote' product pages OR completed diskette with all proposed pricing, AWP, FDA ratings, and manufacturer source filled in for each item bid.
We encourage you to printout the information on the diskette after completed. Send one copy in generic name order with the diskette and keep one for your files. This will ensure that if the diskette is damaged during mailing we will still have bid prices. You do not have to complete the product pages enclosed if you submit a diskette.

D. If you are a new manufacturer/supplier with GeriMed, please enclose information about your company, proof of liability insurance, and any other information pertinent to GeriMed assessing the quality of your company. A new vendor questionnaire, if enclosed, should be completed and returned with your bid.

E. Any special forms or requirements needed in order to add or make a GeriMed member eligible for contract pricing.

F. Your current return goods policy and if you provide for guarantee supply, a procedure for receiving reimbursement by the member.

G. Any other information you feel may assist GeriMed and the GeriMed Advisory Council in making informed decisions regarding your products.

QUOTATION SPECIFICATIONS

1. Acceptance- GeriMed welcomes your participation in the bid process for the 1994 -1996 pharmaceutical contract program. Proposals and bids will be accepted until the close of business on March 28, 1994. If this does not allow you enough time to complete the process, please telephone our offices as soon as possible (502) 423-0351 to request an extension.

2. Negotiated Contracts- Pharmaceutical manufacturers wishing to submit a proposal beyond the straight bid process are urged to contact Susan Rhodus, Vice President of Operations, as soon as possible to discuss the particulars of the proposal. We encourage companies to submit proposals based on volume and/or market share agreements. GeriMed is committed to compliance and increasing market share with contracts that meet our requirements. Requirements and particulars describing the types of contracts needed are discussed in the attached "Request for Incentive Based Proposals".

3. Request for Quote forms and diskettes- Because GeriMed limits the acceptance of members to long term care "closed door" pharmacies only (no retail activity-see enclosed membership criteria for specifics), we ask that you submit the most competitive pricing on the enclosed "Request for Quotation Forms" or via the enclosed bid diskette. This diskette allows your staff and our staff to be more efficient in the bid process. Instructions regarding the diskette are enclosed for your review. A 3.5 inch diskette is enclosed. If you need another size diskette or if you have any questions or problems, please call our offices.

Products are listed on the disk and "Request for Quote" in generic name order. These names are derived from the Generic Product Index in MediSpan files. Prices should be listed for the package size indicated in the package field. If you wish to add other products or package sizes to the bid please follow the directions for the diskette or use the pre-printed forms at the end of the request for quote forms. If a product was bid last year the previous bid price is listed. Items not previously bid will have "0.00" in this column. Please complete all blank spaces on the diskette or printout to ensure we have accurate information on our computer system.

If you find incorrect descriptions, package sizes, etc., please indicate these on the diskette printout or on the request for quote forms so we may update our system. Items that have been discontinued by your company should also be identified on the printout. We will then delete these from our system.

4. Contract length- If awarded, the bid contract prices would begin August 1, 1994. Your quotation must be for a minimum of twelve months with a preference for a two year contract. Longer contracts with a review process to protect GeriMed, GeriMed members, and contracted manufacturers will be considered. Price protection on bid items should be for at least one year with a preference for two year price protection. Price reviews on generic items will be considered if specific guidelines are written by the manufacturers or suppliers for the process of review. For example, " after six months of firm price protection, the manufacturer/supplier may present proposals for price increases based on the cost of raw materials increasing. GeriMed will be given 60 days notice before price increases take effect. An effort to offer price decreases on other contracted products will be made to GeriMed at the same time price increases are proposed. GeriMed has the right to reject the price increase, at which time the product will be removed from the contract."

5. Product Distribution- The method and range of distribution for the manufacturer/supplier is important. GeriMed prefers to have access to contract pricing direct from the manufacturer/supplier and through participating wholesalers. GeriMed members purchase approximately 85% of purchases from wholesalers. Direct purchases, where financially advantageous, are still utilized by many GeriMed members. A list of current GeriMed participating wholesalers is enclosed for your review. Product availability through these wholesalers is important for compliance with the contracts. Wholesalers participating in the GeriMed program are required to sign an agreement stating they will stock items for the GeriMed customer upon request if utilization numbers are provided by the pharmacy.

6. Membership procedures- It is understood that all participating pharmacies are "closed door" servicing only institutional patients. An "own use" statement has been signed by an authorized representative of each member pharmacy. These are on file in our offices for all current members and are available upon request. As new members are added to the contract, GeriMed sends copies of the "own use" statement for each new pharmacy added to the membership list. Each pharmacy must execute an agreement to abide by any restrictions that a manufacturer has regarding eligibility for contract pricing.

GeriMed updates the membership information on a monthly basis. Information with the update includes new members, deleted members, changes in information (new address, DEA, contact person, telephone number, wholesaler, etc.). Contracted manufacturers/suppliers receive notice of new members thirty days before the start of membership. Manufacturers/suppliers with current GeriMed contracts will receive a complete membership list with the April, 1994 membership update.

To ensure updates are received by the correct personnel, please complete the membership personnel section on the first page of the "Request for Quote" sheets. GeriMed expects that a one month advance notice will allow ample time to approve eligibility for new members. Any chargeback refusals or incorrect invoices after the new members effective date must be corrected by credit memo or reimbursement to the member pharmacy. If you have special requirements beyond the ones on the attached membership criteria, please state the requirements in your bid document. Note: Companies with stricter requirements than those stated in the GeriMed Membership Criteria may not be eligible for single source or preferred product status. Please include copies of special forms or applications required to access new members to your contract.

7. Usage information - Estimates of usage for specific products, based on actual member dispensing reports, are available upon request. Please call our offices no later than Friday, March 11th to request these figures.

8. GeriMed Advisory Council - The GeriMed Advisory Council will meet on Thursday, April 21, 1994 to make decisions on contract awards. Fifteen GeriMed members are chosen from the GeriMed membership to serve a two year term on a rotating basis. These members represent many states from east to west and north to south with a variety of distribution systems and number of beds serviced. The Council meets three times a year (usually winter, spring, and fall) to discuss pertinent issues regarding contracting and business opportunities. The April meeting will focus on the new contracts with the Council making decisions on manufacturers/suppliers to contract with, a full line generic company, and any incentive or performance based agreements. Manufacturers/suppliers interested in making a presentation to the Council during our meeting should contact Susan Rhodus immediately.

9. Awards - The following features of each manufacturer/supplier will be reviewed closely before decisions are made:

A. Quality of products -clinical aspects of the drug, manufacturing practices, product consistency, FDA AB ratings, etc.

B. Distribution methods -wholesale and/or direct

C. Availability of product -across the country in wholesalers and/or direct

D. Service-customer service, sales representatives, return good policy, information availability, etc.

E. Guarantee supply -If the manufacturer/supplier cannot supply the product will you reimburse the member if they must purchase a higher priced product? This guarantee does not cover the wholesaler not stocking the item or running out of an item. The shortage must be at the contracted manufacturer/supplier level in order to qualify for the guarantee supply program.

F. Medicaid Rebate Agreement- must be in place for a company to participate in our incentive or performance programs.

G. Contract Administration Fee- We request a 2% fee on all purchases by the members for contracted items. In return for this fee we provide the following services - onsite visits to all new members to ascertain "closed door" status; a suggested formulary and invoice review service to reinforce contract compliance; quality assurance; drug usage analysis from wholesaler and dispensing records; administration of performance and incentive based programs.

It is understood that participation in this program by the manufacturer/supplier will not affect the pricing to the GeriMed members. Payments of this fee are due 30 to 45 days after the end of each quarter or month as you designate. Two reports on sales to GeriMed members are requested: 1) line item by member per month or quarter 2) line item consolidated for the entire group by product by month or quarter. Both reports should show dollar volume as well as number of units sold. If this information is available on diskette or modem in an ASCII format please contact our office as soon as possible to set up a format and transmission.

H. Low price and best spreads - Contract pricing will be evaluated on lowest price and/or best spread between AWP and the contract price for multisource products. Manufacturers/suppliers interested in obtaining a single source award should consider sending in a performance or incentive package for one or more products. Most multisource products (without a special program) will receive a dual award since we will be contracting with one full line generic company in addition to other manufacturers and/or suppliers.

11. **Bid Analysis** - All bids and proposals received by GeriMed will be held confidential. The submitted quotations will be analyzed by computer using our database program showing all quotations submitted for each generic name and package size. The GeriMed Advisory Council will review all submitted quotations and have an opportunity to select the manufacturers/suppliers to be on contract as well as choosing preferred products and incentive programs. Quotations will be analyzed on line-by-line basis. Please note that GeriMed may accept or reject any portion or all of the quotation. Companies demonstrating the best quality, policies, programs and price will be favored (see above evaluated characteristics).

12. **Submission of quotations constitutes a legal offer** - and therefore, if any of your quotations are accepted, and in exchange for being designated as participant in the GeriMed program, your company agrees to be legally bound to provide each GeriMed member pharmacy- present and approved in the future - on an as-needed basis, any items encompassed on your accepted quotations pursuant to the terms of the respective quotation as designated in the awards document to be sent by GeriMed. Bids will be kept open until July 31, 1994. Awards will be made near the end of May, 1994.

Please feel free to contact our offices if you have questions or need further information (502) 423-0351.

March 8, 1996

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Dear Contracts Administrator:

Please accept the following bid package as a formal request for quotation to GeriMed. GeriMed is a group purchasing organization designed for pharmacies servicing the long term care patients with pharmaceuticals in a "closed door" setting. Many of these pharmacies also service nursing homes with IV therapy.

I request that you read all the materials carefully before pricing your products for GeriMed. GeriMed currently contracts with 130 pharmaceutical manufacturers (brand and generic companies) and suppliers for the 1994 - 1996 contracts. GeriMed, as of April 1, 1996, has more than 470 pharmacy members in 41 states servicing more than 720,000 beds. We continue to add between 5 and 10 new members monthly.

GeriMed

9707 Shelbyville Road
Louisville, Kentucky 40223
502-423-0351
502-339-1417 FAX

Please find enclosed the following information: 1) an introduction to GeriMed with service programs described 2) GeriMed membership criteria 3) instructions for submission of quotes 4) a 3.5 in diskette for the bids with instructions 5) "Request for Quotation" document 6) two copies of our supplier agreement 7) participating wholesalers.

Bids are due at close of business on **March 29, 1996.** Performance agreements are due at close of business **April 15, 1996.** Please let us know if these due dates present any problems. Contracts awarded will begin on August 1, 1996 and end July 31, 1998.

Thank you for your time and expertise on this bid. GeriMed looks forward to continuing or beginning a great relationship with you during the next year.

Sincerely,

Susan M. Rhodus, R.Ph.
Vice President of Operations

Enclosures

Geriatric Healthcare
Containment

CONFIDENTIAL

GeriMed Request for Proposal

Prepared for
Bidding Pharmaceutical Manufacturers and Suppliers

by
Susan M. Rhodus, R.Ph., Vice President of Operations

March 8, 1996

CONFIDENTIAL

Table of Contents

1

Introduction

This document contains all the information you need to submit a proposal for bid to GeriMed.

Dates to Remember

- March 29, 1996 - Bid documents due at GeriMed offices
- April 15, 1996 - Special incentive programs due at GeriMed offices
- April 25 - 27, 1996 - GeriMed Advisory Council Meeting
- June 5, 1996 - Awards faxed to manufacturers (tentative)
- June 12, 1996 - Final proof of awards due at GeriMed offices (tentative)
- August 1, 1996 - Contract start date for new GeriMed awards

Contents of This Proposal

- History and Corporate Goals of GeriMed
- GeriMed Membership Criteria
- List of Manufacturers currently under contract
- GeriMed Journal, EmphaSys, and GeriMax Marketing Pieces
- Instructions and Specifics for Bid Submission
- Incentive or Performance Contract Criteria
- Computer diskette 3.5" for bid entry with instructions
- Request for Quote document listing your company's products with request for special information (i.E. contacts, distribution, special terms, etc.)
- Two copies of the GeriMed agreement for execution with the bid submission
- Wholesaler list as of April 1, 1996

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GeriMed History and Corporate Goals

Introduction

GeriMed is a group purchasing organization designed specifically for long term care "closed door" pharmacy providers. GeriMed was established in 1983 as a joint venture between MedEcon (a hospital buying group) and H. Joseph Schutte, R.Ph. Joe Schutte, President and owner of GeriMed has been in the long term care pharmacy business for more than thirty years. As the innovator in long term care pharmacy group purchasing, GeriMed has developed services and contracts to meet the needs of customers throughout the years.

As you know, healthcare is changing on a minute by minute basis. GeriMed's goal is to meet the challenge of ensuring its customers the best services, best contract pricing, while netting more profit for the member and contracted pharmaceutical manufacturers. In order to meet the customers needs in the future, GeriMed must go beyond simple contracting for pharmaceutical products for long term care pharmacies. The conversion of GeriMed from a group purchasing organization (GPO) to a group service organization (GSO) is the first step in adapting GeriMed for the future.

Corporate Philosophy

Mission Statement

This mission statement gives GeriMed a basis to establish new and innovative services to benefit both its membership and pharmaceutical manufacturer partners.

" Through long-term partnerships in the health care industry, GeriMed provides access to cost effective solutions which support our clients' efforts to improve their strategic position, financial performance, and quality of care"

Governing Values and Goals

GeriMed has set values and goals in order to achieve this innovative approach to contracting. Our goals for the company are attained by following three solid values.

- **Professionalism and Integrity** - To maintain professionalism and integrity in the marketplace by:
  - * Focusing and committing to support the health care industry and professional associations by standing by membership criteria, communicating information and participating in professional associations
  - * Demonstrating a continued commitment to the most cost effective treatments allowing positive patient care

- **Customer Driven Company** - To develop a partnership with each member in achieving financial success by:
  - * Continuing to have a knowledgeable and motivated customer support team through training, advanced technology, and teaching programs for members
  - * Developing positive relationships between customers and industry partners through meetings and environments conducive to negotiations and education

- **Financial Success** - To run an efficient, service-oriented, customer-driven company by:
  - * Continuing to develop the best contracts and cost containment solutions through innovative contracts, customer specific programs, and routine profit maximization analysis
  - * Fostering and supporting entrepreneurial innovation in our partners' businesses through innovative strategies for revenue enhancement and providing access to experts in these strategies

GeriMed Advisory Council

One avenue to ensure our services meet the needs of our members is through our Long Term Care Advisory Council, which meets three times a year. Members of this council are in constant contact with GeriMed regarding legislative changes, regulation updates, and suggestions in contracting. The Council makes decisions on contracts and special programs developed for the membership. GeriMed participates in legislative issues, meets with advocates of the long term care pharmacy concerns in Washington, D.C., and keeps current with updates in healthcare reform.

General Information

Membership

GeriMed currently has more than 470 member pharmacies representing more than 300 corporations or pharmacies systems in 41 states. These pharmacies currently service

more than 720,000 long term care beds. Our members consistently outperform other group purchasing organizations in compliance (calculated on dollars per bed). This compliance rate demonstrates the loyalty of GeriMed members.

GeriMed prides itself in accepting only closed door pharmacies servicing patients in a long term care setting. We are the only group purchasing organization that visits each pharmacy location before membership begins to ensure closed door status. GeriMed also monitors purchases to ensure appropriate use by the members. GeriMed works with manufacturers and investigates inconsistencies in purchases and dispensing. Protecting and monitoring the integrity of the group is important to guarantee that the manufacturers continue their partnerships with our group and its members.

Types of Customers Services by GeriMed Members

Because the focus of long term care pharmacy practice has expanded beyond geriatric patients in nursing homes, GeriMed has expanded its services, too. Contracts to address the needs of jails and prisons, home care, mentally retarded, hospice, and sub-acute patients have been added throughout the years. Expansion of GeriMed's services and contracts to meet the expanding needs of its membership is a continuing goal of the company. The contracts include a full line of parenteral and enteral products, pump rentals, plastics for parenteral and enteral, packaging alternatives, forms, medical supplies, urologicals, and other miscellaneous products. GeriMed membership entities the member access to all contracts-both pharmaceutical and non-pharmaceutical.

GeriMed Services

GeriMed believes we deliver the best contracts in the country for long term care providers. Our extra services continue to expand to meet the needs of our members. Many of our services are described below:

EmphaSys

For more than three years GeriMed has had a stand alone electronic catalog program. This software is run with an IBM DOS operating system and allows the member to view the entire catalog via a computer. While this system offers a mechanism to view contract items, it can be tedious in this DOS format.

GeriMed recently announced the release of a new software product - **EmphaSys.** This program is written under the Windows operating system. It is much easier to use and allows the member to utilize the system to choose appropriate products for their purchasing. This tool can enhance revenue and decrease costs. Members can view item codes for their wholesaler, view products with the best spread and lowest cost, or open multiple windows to compare data.

Products can be sorted in four fashions - by trade name, by generic name, by manufacturer or supplier and by therapeutic class. A single drug can be found by typing

in part or all of the drug name. Updates to pricing, AWPs, NDC#s, etc. are provided monthly. Diskettes are sent according to the state requested, giving the member information on the state MACs. Members can print selected products, make a formulary, input usage, and input exact reimbursement compared to the MACs listed by MediSpan. With more than 9,000 line items, this system offers an efficient and accurate mechanism to utilize the contracts.

Invoice Analysis

GeriMed offers a quarterly review of invoices for all pharmaceutical purchases by member pharmacies. This review is a compliance tool to ensure the pharmacies are purchasing the most cost effective products available on contract. Several items are identified during the review including price errors by the wholesaler, lower priced generic products, better package size or type, therapeutic substitution opportunities, etc. These suggestions are made to save money through lower contract pricing or increase revenue through better spread between AWP and contract price. This review is done from a monetary perspective only; special state regulations, clinical concerns, and other input must be included when reviewing changes.

Incentive Programs

GeriMed continues to update, refine, and develop new and exciting ways of contracting. Incentive programs are allowing GeriMed members to take advantage of a broader spectrum of pharmaceuticals. We have added more than 40 manufacturers and suppliers to our incentive contracts in less than four years. The incentive programs will be reviewed and revised to meet the changing needs of our membership. (See chapter 5 for more details on these exciting programs).

GeriMax

A new program, announced to members in January, 1995, is **GeriMax**. **GeriMax** is a special program combining special market share contracts with additional services and data analysis. This program is open to all members of GeriMed. Members wanting to access the special **GeriMax Agreements** and special services must commit to the GeriMed contract for forty-two of fifty chosen contracts. GeriMed is looking for compliance from the membership in order to justify special services to the membership. Manufacturers want to work with compliant customers. The commitment is only to use the GeriMed contracts - market share and volume commitments are made at the individual contract level.

Once a member commits to **GeriMax**, they have access to the following special services:

GeriMax Agreements - These contracts reward maximum performance with maximum discounts. **GeriMax** members receive contracts with a choice of three tiers of commitment - **GeriMax**, Committed, and Uncommitted. After reviewing the clinical and financial aspects of the agreements, a reasonable commitment can be made to one of the three tiers. Manufacturers are also dedicated to these agreements by providing

information, education, and marketing expertise, forming a true partnership. Manufacturers interested in pursuing a **GeriMax** agreement should contact GeriMed as soon as possible. These agreements are in addition to our regular incentive programs and will be negotiated on a one to one basis with manufacturers looking to partner with GeriMed.

Formulary Setup and Operational Analysis - GeriMax provides consulting services to implement compliance programs. Specific programs can be developed by both parties to ensure the needs of the member are met. These strategies can include discussions of incentive programs, suggestions on maximizing profitability with a buying group, or special programs designed specifically to meet the unique needs of the client.

Reimbursement assistance - The GeriMed binder and **EmphaSys** system provide item by item detail printouts and screens with the state MACs and calculations per state. The GeriMed program identifies the lowest cost product and the best spread for the particular state. Our network of pharmacy members across the country and contacts with manufacturers allows us to keep up with new regulations throughout the country. Members asking about reimbursement in a particular state can obtain the information by calling the **GeriMax** staff. **GeriMax** can assist a member by completing a special formulary designed especially for their situation. A special list of questions assist the **GeriMax** staff in determining the best product for purchase.

Clinical research - Because of our partnership relationships with many members, **GeriMax** can assist manufacturers in gaining access to members interested in participating in educational and research programs for geriatric and other types of research. Many pharmaceutical companies are interested in geriatric research but are unsure of who to contact in long term care pharmacy practice.

Data Management - The most difficult aspect of contracting especially performance based contracting, is proving market share movement. In addition, members want to know how they are progressing on market share agreements. Our new data system collects information from each wholesaler. Data can be provided to manufacturers and members at the NDC number level. Sorting the data by generic name or therapeutic class can be accomplished. Providing days of therapy and units per bed can be added for manufacturers looking for extra detail. **GeriMax** members committing at the **GeriMax** level will receive regular reports of how they are progressing with market share.

Implementing innovative programs and improving methods of communication to our membership is a constant challenge. Recently we began using fax broadcast to alert members of immediate and important contract information. We are testing a computer program that allows members to access contract pricing via modem. Methods of supplying unique and superior clinical and research information are also being examined.

GeriMed membership enables long term care "closed door" pharmacies to benefit from years of integrity, outstanding service, and low contract pricing. Being a member of GeriMed allows a member to assign staff to other more important duties than reviewing invoices, imputing contracts in computers, checking eligibility on contracts, and making

sure the member is getting the best deal in pharmaceutical purchasing. GeriMed becomes an extension of the members' staff and develops a partnership relationship that can benefit both companies.

Contracting Process

GeriMed requests contracts from pharmaceutical manufacturers and suppliers biannually through a bid process. Manufacturers submitting bids must offer a minimum of one year contract or a maximum of two years. GeriMed has developed many partnership relationships with manufacturers over the years. These partnerships many times allow us to be the first group purchasing organization with unique powerful contracts. We encourage interested manufacturers to develop negotiated contracts that consider volume and market share contracting. Many manufacturers have responded with incentive or performance based contracts. While straight line by line contracting is preferred by members and GeriMed, we see this type of contracting decreasing. Manufacturers are looking for increases in volume and market share to justify contracting with any type of provider (including managed care and hospitals). Demonstrations of changes in volume and market share are accomplished by collection of purchasing data from participating wholesalers. GeriMed then becomes the administrative center to analyze and forward the data to the appropriate manufacturers with performance contracts. Payment to each member is made based on performance for each contract. Systems have been developed to collect this data on an efficient basis from the wholesalers.

Development of contracts by choosing a drug in a specific therapeutic class as a preferred product can help GeriMed gain better contracts and discounts. GeriMed's philosophy, supported by the Advisory Council, mandates three parts in the decision making process to choose a specific drug as preferred.

1. **Clinical efficacy** - This is by far the most important requirement of the drug product. The product must demonstrate, through reliable, credible sources to be as efficacious as other products in its class. Preference is shown to products with data relating to the geriatric population, although this is usually a difficult requirement. The Advisory Council recently decided to set up a Pharmacy and Therapeutics Committee made up of clinical and consultant pharmacists from the Council's pharmacies. Data will be sought from unbiased sources to conduct a review of the therapeutic class identified.

2. **Patient cost/compliance** - Healthcare reform has made medication cost more important to the patient, third party payor, care giver, and healthcare professionals including physicians. If a product offers a lower cost to the patient or third party without sacrificing clinical efficacy, it becomes easier for the consultant pharmacist to make a recommendation to the physician. Lower cost does not necessarily mean a lower price for the product. It could be that the cost per day is less, or it is easier for the nursing staff to administer in a time efficient manner. Although medications are administered in a controlled environment within the nursing home or at home for most patients serviced by GeriMed members, patients can still refuse medications that cause unpleasant side effects, are difficult to swallow, etc. Providing a more palatable or side effect free medication may result in cost savings to the patient

indirectly. Cost effectiveness of patient care is also an important aspect of cost to the patient. If a product can reduce the number of days for rehabilitation, decrease the number of hospital admissions, or eliminate other more costly therapies (i.e. surgery, laboratory tests, medical devices, etc.) then it should be considered a cost effective product.

3. **Increase revenue or decreased cost for the pharmacy** - Finally, the member pharmacy must have an incentive to promote and perform with the product. Costs for consultant pharmacists to administer a therapeutic interchange or appropriate therapy program can add up. Profitability of the company becomes important to support the progressive services provided by a long term care pharmacy provider. Therefore, these incentive programs are evaluated on the merits of their profitability to the pharmacy.

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AWP REIMBURSEMENT PROMOTION

FOR GERIMED

PROPOSAL TO GERIMED

SITUATION ANALYSIS

- TOTAL DOSES OF ALBUTEROL SOLD TO MEMBERS DURING REPORTING PERIOD 4/1-6/30 95 (3 MONTHS) -2,012,230
- TOTAL UNIT DOSE - 1,249,590 OR 62%%
- TOTAL MULTI DOSE- (DOSES =UNITS X 2) -762,640 OR 38%
- DEY HAD 68.9% OF UNIT DOSE SHARE
- WARRICK HAD 29% OF MULTIDOSE SHARE
- DEY HAS 43% SHARE OF ALL ALBUTEROL DOSES (MD AND UD)

RECOMMENDATIONS

- MOVE MULTIDOSE MARKET TO UNIT DOSE STERILE BAC FREE DEY USING PROVIDED PROFIT COMPARISON CHART
- CONVERT COMPETITIVE UD TO DEY UD WITH REBATE INCENTIVE

ADVANTAGES

- NO MIXING, REDUCES LABOR, STERILITY, NO CROSS CONTAMINATION, NO FOAMING, SHORTER NEBULIZER TIME
- COST SAVINGS - NO WASTE, HIGHER AWP REIMBURSEMENT
- IMPROVE QUALITY OF CARE
- IMPROVE GERIMED ADMINISTRATION REVENUE

THE PROGRAM

- **DEY SHARE FOR ALL DOSES IS 43%**

DEY WILL PAY A MARKET SHARE REBATE TO ITS COMMITTED MEMBERS BASED ON A DETAIL REPORT PROVIDED BY GERIMED IF THE FOLLOWING SALES OBJECTIVES ARE REALIZED BETWEEN JANUARY 1,1996 AND DECEMBER 31, 1996
TOTAL ALBUTEROL DOSES PURCHASES FROM DEY BY INDIVIDUAL MEMBER

43-49% OF TOTAL	NO REBATE
50-59% OF TOTAL	.01 A VIAL
60-84% OF TOTAL	.02 A VIAL
85% AND ABOVE	.04 PER VIAL OF DEY PRODUCT SOLD IN QUARTER

*MARKET SHARE FOR EACH MEMBER WILL BE CALCULATED BY GERIMED AND AUDITED BY DEY EACH QUARTER AND REBATES WILL BE PAID PER ABOVE SCHEDULE UPON MARKET PERCENTAGE FOR THAT QUARTER

EACH MEMBERS MARKET SHARE REBATE WILL BE PAID INDIVIDUALLY BY GERIMED. DEY WILL PAY GERIMED A LUMP SUM REBATE BASED ON INDIVIDUAL PERFORMANCE AND GERIMED WILL DISTRIBUTE TO ITS COMMITTED MEMBERS ACCORDING TO THEIR INDIVIDUAL PERFORMANCE

THE COMMITTED LIST IS SUBJECT TO DEY APPROVAL AND ALTHOUGH CURRENT DEY LABS CUSTOMERS ARE ELIGIBLE, THE INTENT OF THIS PROGRAM IS TO GAIN ALBUTEROL MARKET SHARE BY CONVERTING MULT-DOSE USERS AND COMPETITIVE UNIT DOSE USERS TO DEY

*MARKET SHARE IS DEFINED BY TOTAL ALBUTEROL DOSES PURCHASED BY MEMBER DURING REPORTING PERIOD

IMPROVED PROFIT AND BETTER PATIENT CARE BY USING UNIT DOSE

VS

MULTIDOSE IN LTC PHARMACY

EXAMPLE

PHARMACY CONTRACT (20 ML VIAL WARRICK-40 TREATMENTS IN VIAL)
= $7.40 COST PER VIAL

COST
$ 7.40 ÷ 40 = .19 A TREATMENT
+ .02 SALINE USED AS DILUTENT

= .21 A TREATMENT

$9.75 ÷ 25 = .39 COST OF UNIT DOSE PREMIXED ALBUTEROL ON DEY LABS CONTRACT
= .39 A TREATMENT

REIMBURSEMENT = AWP
$12.50 ÷ 40 = .31 A TREATMENT
+.02 SALINE USED AS DILUTENT
=.33 A TREATMENT

$30.25 ÷ 25 = **1.21 A TREATMENT**

SPREAD = AWP - COST
.12 A TREATMENT WITH MULTI DOSE
.82 A TREATMENT WITH UNIT DOSE

THE DIFFERENCE: .70 A TREATMENT MORE REIMBURSEMENT WITH UNIT DOSE

ADMINISTRATION FEE IMPROVEMENT
BY SELLING UNIT DOSE ON CONTRACT

VS

MULTIDOSE

EXAMPLE - WARRICK CONTRACT COST @ $7.40 20 ML VIAL

$7.40 X 5,559(3M) = $41,136 X .02=$822

$10.00 X 8894 (3M) = 88,940 X .02=$1,778

- CUSTOMER WINS: **INCREASES PROFIT OVER 5 TIMES**
- GERIMED WINS: **INCREASE YOUR TOTAL SALES DOLLARS WHICH INCREASE YOUR ADMINISTRATION FEES**
- DEY WINS: **INCREASES OUR MARKET SHARE AND SALES TO GERIMED**

PHARMACEUTICAL MANUFACTURERS WARRICK AND DEY's USE OF THE "SPREAD" TO CAPTURE THE STATE OF FLORIDA'S MEDICAID MARKET FOR ALBUTEROL 0.083%

Manufacturer	True Cost per ml	Florida Medicaid Reimbursement per ml	The "Spread"	# of claims	Reimbursement paid by Florida Medicaid
Warrick	$0.1065	$0.3590	$0.2525	12,673	$763,595.42
Dey	$0.1125	$0.3531	$0.2406	9,792	$707,220.50
Zenith/Goldline	N/A	$0.2138	**	102	$4,981.86
Geneva	N/A	$0.1787	**	19	$1,278.08
TOTAL REIMBURSEMENT BY THE STATE OF FLORIDA MEDICAID PROGRAM (January 1 through March 31, 1997)					$1,477,075.86

**, THE USE OF THE "SPREAD" TO CAPTURE MARKET SHARE IS EVIDENCED BY THE FACT THAT WARRICK'S AND/OR DEY'S CUSTOMERS WILL RECEIVE MORE PROFIT BY PURCHASING WARRICK'S AND/OR DEY'S ALBUTEROL THAN IF ZENITH/GOLDLINE OR GENEVA GAVE THEIR CUSTOMERS THEIR ALBUTEROL FOR FREE.

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Ipratropium Bromide 0.02% Sol.

HCPCS code J7645 & (K0518)

YEAR	MEDICARE REIMBURSEMENT AMOUNT PER UNIT*	Ven-A-Care COST PER MEDICARE UNIT	"SPREAD" (PROFIT) $	"SPREAD" (PROFIT) %	MEDICARE ALLOWABLE $
1995	$ 3.11 mg. ($0.62/ml)	$3.11	$0.00	0%	$14,426,108
1996	$ 3.75 mg. ($0.75/ml)	$3.26	$0.49	15%	$47,388,622
1997	$ 3.50 mg. ($0.70/ml)	$2.15	$1.35	63%	$96,204,639
1998	$ 3.34 mg.	$1.70	$1.64	96%	$176,887,868
1999	$ 3.34 mg.	$1.60	$1.74	108%	$253,400,414
2000	$ 3.34 mg.	$0.94	$2.40	255%	$347,527,960
2001	$ 3.34 mg.	$0.82	$2.52	307%	

* Medicare Units were converted from ml's to mg's for the years 1995,1996 &1997
(5 ml=1 milligram) &
1998-2001 @ 95% of AWP

p. 1

Ipratrop-Medicare-01.wpd

Albuterol Sulfate 0.083%

HCPCS codes J7619 & (K0505)

YEAR	MEDICARE REIMBURSEMENT AMOUNT PER UNIT*	Ven-A-Care COST PER MEDICARE UNIT	"SPREAD" (PROFIT) $	"SPREAD" (PROFIT) %	MEDICARE ALLOWABLE $
1994	$ 0.492 mg. ($0.41/ml)	$ 0.38	$ 0.113	29%	$147,867,789
1995	$ 0.516 mg. ($0.43/ml)	$ 0.244	$ 0.272	111%	$166,901,971
1996	$ 0.492 mg. ($0.41/ml)	$ 0.244	$ 0.248	101%	$178,411,078
1997	$ 0.492 mg. ($0.41/ml)	$0.19	$ 0.303	160%	$199,763,937
1998	$ 0.47 mg.	$ 0.16	$ 0.31	193%	$230,376,027
1999	$ 0.47 mg.	$ 0.14	$ 0.33	233%	$248,844,463
2000	$ 0.47 mg.	$ 0.08	$ 0.39	487%	$295,661,130
2001	$ 0.47 mg.	$ 0.07	$0.40	571%	

* Medicare Units were converted from ml's to mg's for the years 1994-1997 (3 ml = 2.5 milligram) & 1998-2001 @ 95% of AWP

Albuterol-01-Medicare.wpd

P-2

DEPARTMENT OF HEALTH & HUM

Office of Inspector General

Q1

Memorandum

Date DEC 13 1999

From June Gibbs Brown
Inspector General

Subject Infusion Therapy Services Provided in Skilled Nursing Facilities (A-06-99-00058)

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

Attached are two copies of our final report entitled, "Infusion Therapy Services Provided in Skilled Nursing Facilities." The objective of this audit was to determine if infusion therapy services provided by some infusion suppliers to Medicare-reimbursed skilled nursing facilities (SNF) were reasonably priced, medically necessary, and classified correctly on the cost reports. Our review of three infusion suppliers, for the period 1995 through 1998, showed they provided infusion therapy services to Medicare-reimbursed SNFs that were excessively priced and unnecessary. In addition, the three infusion suppliers billed certain infusion services incorrectly, causing those costs to be misclassified on the SNFs' cost reports. This occurred because the reimbursement system was vulnerable to abusive billing schemes. As a result, patients were placed at undue risk, Medicare overpaid the SNFs, and the overpayments may have been included in the base year costs used to establish the prospective payment system (PPS) rates.

The three infusion suppliers reviewed charged SNFs excessive prices for infusion therapy, provided unnecessary infusion services to SNF patients, and improperly billed SNFs for nursing services that the SNFs, in turn, misclassified on the Medicare cost reports.

The SNFs billed Medicare for these unallowable costs. To quantify the impact to Medicare, we reviewed claims submitted by 22 SNFs that used various infusion therapy suppliers. The vast majority of infusion services were provided by two of the three infusion therapy suppliers reviewed in this audit. At the 22 SNFs, $4.8 million out of $9 million in claims reviewed (53 percent) were not medically necessary. An additional $332,000 in payments that were found to be medically necessary were questioned because the prices exceeded the prevailing rate. Finally, another $158,000 was questioned because routine costs were misclassified as ancillary costs on the SNF cost reports.

The three infusion therapy suppliers we reviewed accounted for at least $138 million, or approximately 20 percent, of all infusion therapy costs reimbursed by Medicare nationwide during 1995 through 1998. Because these infusion therapy suppliers employed the same

billing practices with hundreds of SNFs in several States, we are concerned that additional unallowable costs were paid by Medicare during this period. We also have concerns that these abusive practices may have resulted in inflated base year costs upon which the PPS rates were based.

In addition to the financial effects we noted above, overutilization and overpricing were potentially harmful to the patients. Medical reviewers who were a part of our audit concluded that patients receiving unnecessary infusion services were placed at undue risk for complications, including increased risk of infection, fluid and electrolyte imbalance, and medical reactions. Furthermore, infusion services are invasive procedures that are painful and, when unnecessary, reduce the quality of life.

One of the three infusion suppliers has entered into a $10 million settlement agreement with the Government to resolve its civil liability under the False Claims Act and Civil Monetary Penalties Law which involved delivery of infusion services in Texas and in other States. The other infusion suppliers and many nursing homes are the subjects of additional audits and investigations by the Office of Inspector General (OIG), the fiscal intermediary, and/or the Federal Bureau of Investigation.

Prior to 1998, Medicare paid nursing homes through a retrospective, reasonable cost-based system. As our results showed, this system was vulnerable to abusive billing schemes because providers were reimbursed based on their costs, thus giving them a strong incentive to provide unnecessary and overpriced services to increase their Medicare payments. Abusive billing arrangements between SNFs and infusion suppliers resulted in tremendous profits which encouraged the overutilization of infusion services when no treatment was necessary.

Section 4432(a) of the Balanced Budget Act of 1997 required implementation of a Medicare PPS for SNFs. In 1998, the Health Care Financing Administration (HCFA) implemented the SNF PPS for cost reporting periods beginning on or after July 1, 1998. Accordingly, payments are no longer based on the reasonable cost-based system, but rather are based on a fixed per diem which is adjusted for the patient's acuity level. The PPS rates were based on mean SNF costs for cost reporting periods beginning in Fiscal Year 1995. Recently, nursing home officials have expressed concern that reimbursements under PPS for high-cost services, including infusion services, are too low and thus quality of care may be compromised. Various alternatives for changing PPS rates are being discussed.

While our audit did not focus on the accuracy of the PPS rates for infusion therapy, we want to bring the results of our audit work to your attention should HCFA decide to change the reimbursement rates. We believe the adoption of PPS should help to correct the problem of SNFs and suppliers engaging in abusive billing schemes to increase Medicare reimbursements. However, PPS rates that do not reasonably reflect the SNFs' costs of providing services could still result in financial windfall to the SNFs. Under PPS, patients

may still be subjected to unnecessary services. This could occur if unnecessary infusion therapy services were performed which may increase the patient's classification of services to a higher payment level within the PPS structure. Thus, more patients may be harmed by unnecessary infusion therapy.

We are concerned that unallowable infusion therapy costs may have resulted in inflated base year costs upon which the PPS rates were based. Furthermore, we believe reimbursement levels for infusion therapy that are too high affect quality of care due to overutilization, just as low reimbursement affects quality of care through underutilization. Therefore, before the PPS rates for infusion therapy are modified, we believe that the unallowable costs identified in this report should be seriously considered.

Accordingly, we recommend that HCFA:

- consider the impact of improper payments for infusion therapy services before making any refinements or updates to the SNF PPS rates. In addition, if legislative changes are adopted which mandate the use of cost reimbursement for infusion services, work with the OIG to quantify a possible national error rate for infusion therapy services;

- identify and recover overpayments which were made to SNFs for unnecessary and overpriced infusion services prior to the adoption of PPS; and

- direct its contractors to perform medical reviews of selected SNF patients to ensure that patients are receiving appropriate levels of infusion therapy.

In response to our draft report, HCFA generally agreed with our recommendations. In response to part of one recommendation, HCFA raised concerns about the benefit of establishing a national error rate for a set of services that is bundled with other sets of services into a single per diem rate under PPS. To take into account HCFA's comments, we changed our report to recommend a national error rate calculation in the event that Congress adopts legislation which mandates the use of cost reimbursement for infusion services. The complete text of HCFA's response is included as Appendix A to the report.

Please advise us within 60 days of actions taken or planned on our recommendations. If you have any questions, please contact me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 786-7104.

To facilitate identification, please refer to Common Identification Number A-06-99-00058 in all correspondence related to this report.

Attachments

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

INFUSION THERAPY SERVICES PROVIDED IN SKILLED NURSING FACILITIES

JUNE GIBBS BROWN
Inspector General

DECEMBER 1999
A-06-99-00058

DEPARTMENT OF HEALTH & HUMAN SERVICES — Inspector General

Memorandum

Date DEC 13 1999

From for June Gibbs Brown
Inspector General

Subject Infusion Therapy Services Provided in Skilled Nursing Facilities (A-06-99-00058)

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

This final report provides you with the results of our audit of infusion therapy services provided to Medicare beneficiaries residing in skilled nursing facilities (SNF). The objective of the audit was to determine if infusion therapy services provided by some infusion suppliers to Medicare-reimbursed SNFs were reasonably priced, medically necessary, and classified correctly on the cost reports. Our review of three infusion suppliers, for the period 1995 through 1998, showed they provided infusion therapy services to Medicare-reimbursed SNFs that were excessively priced and unnecessary. In addition, the three infusion suppliers billed certain infusion services incorrectly, causing those costs to be misclassified on the SNFs' cost reports. This occurred because the reimbursement system was vulnerable to abusive billing schemes. As a result, patients were placed at undue risk, Medicare overpaid the SNFs, and the overpayments may have been included in the base year costs used to establish the prospective payment system (PPS) rates.

The three infusion suppliers reviewed:

- charged SNFs substantially more than prevailing rates for infusion therapy services;
- provided infusion therapy services to Medicare patients that were not medically necessary; and
- improperly billed the SNFs for nursing services, which the SNFs misclassified as ancillary expenses on their cost reports.

The SNFs, in turn, billed Medicare for these unallowable costs. To quantify the impact to Medicare, we reviewed claims submitted by 22 SNFs that used various infusion therapy suppliers. The vast majority of infusion services were provided by two of the three infusion therapy suppliers reviewed in this audit. At 22 SNFs, $4.8 million out of $9 million in claims reviewed (53 percent) were not medically necessary. An additional $332,000 in payments that were found to be medically necessary were questioned because the prices

exceeded the prevailing rate. Finally, another $158,000 was questioned because routine costs were misclassified as ancillary costs on the SNF cost reports.

The three infusion therapy suppliers we reviewed accounted for at least $138 million, or approximately 20 percent, of all infusion therapy costs reimbursed by Medicare nationwide during 1995 through 1998. Because these infusion therapy suppliers employed the same billing practices with hundreds of SNFs in several States, we are concerned that additional unallowable costs were paid by Medicare during 1995 through 1998. We also have concerns that these abusive practices may have resulted in inflated base year costs upon which the SNF PPS rates were based.

In addition to the financial effects we noted above, overutilization and overpricing were potentially harmful to the patients. Medical reviewers who were a part of our audit concluded that patients receiving unnecessary infusion services were placed at undue risk for complications, including increased risk of infection, fluid and electrolyte imbalance, and medical reactions. Furthermore, infusion services are invasive procedures that are painful and, when unnecessary, reduce the quality of life.

One of the three infusion suppliers has entered into a $10 million settlement agreement with the Government to resolve its civil liability under the False Claims Act and Civil Monetary Penalties Law which involved delivery of infusion services in Texas and in other States. The other infusion suppliers and many nursing homes are the subjects of additional audits and investigations by the Office of Inspector General (OIG), the fiscal intermediary, and/or the Federal Bureau of Investigation.

Prior to 1998, Medicare paid nursing homes through a retrospective, reasonable cost-based system. As our results showed, this system was vulnerable to abusive billing schemes because providers were reimbursed based on their costs, thus giving them a strong incentive to provide unnecessary and overpriced services to increase their Medicare payments. Abusive billing arrangements between SNFs and infusion suppliers resulted in tremendous profits which encouraged the overutilization of infusion services when no treatment was necessary.

Section 4432(a) of the Balanced Budget Act of 1997 (BBA) required implementation of a Medicare PPS for SNFs. In 1998, the Health Care Financing Administration (HCFA) implemented the SNF PPS for cost reporting periods beginning on or after July 1, 1998. Accordingly, payments are no longer based on the reasonable cost-based system, but rather are based on a fixed per diem which is adjusted for the patient's acuity level. The PPS rates were based on mean SNF costs for the cost reporting periods beginning in Fiscal Year (FY) 1995. Recently, nursing home officials have expressed concern that reimbursements under PPS for high-cost services, including infusion services, are too low and thus quality of care may be compromised. Various alternatives for changing PPS rates are being discussed.

While our audit did not focus on the accuracy of the SNF PPS rates for infusion therapy, we want to bring the results of our audit work to your attention should HCFA decide to change the reimbursement rates. We believe the adoption of PPS should help to correct the problem of SNFs and suppliers engaging in abusive billing schemes to increase Medicare reimbursements. However, PPS rates that do not reasonably reflect the SNFs' costs of providing services could still result in financial windfall to the SNFs. Under PPS, patients may still be subjected to unnecessary services. This could occur if unnecessary infusion therapy services were performed which may increase the patient's classification of services to a higher payment level within the PPS structure. Thus, more patients may be harmed by unnecessary infusion therapy.

We are concerned that unallowable infusion therapy costs may have resulted in inflated base year costs upon which the PPS rates were based. Furthermore, we believe reimbursement levels for infusion therapy that are too high affect quality of care due to overutilization, just as low reimbursement affects quality of care through underutilization. Therefore, before the PPS rates for infusion therapy are modified, we believe that the unallowable costs identified in this report should be seriously considered.

Accordingly, we recommend that HCFA:

- consider the impact of improper payments for infusion therapy services before making any refinements or updates to the SNF PPS rates. In addition, if legislative changes are adopted which mandate the use of cost reimbursement for infusion services, work with the OIG to quantify a possible national error rate for infusion therapy services;

- identify and recover overpayments which were made to SNFs for unnecessary and overpriced infusion services prior to the adoption of PPS; and

- direct its contractors to perform medical reviews of selected SNF patients to ensure that patients are receiving appropriate levels of infusion therapy.

In response to our draft report, HCFA generally agreed with our recommendations. In response to part of one recommendation, HCFA raised concerns about the benefit of establishing a national error rate for a set of services that is bundled with other sets of services into a single per diem rate under PPS. To take into account HCFA's comments, we changed our report to recommend a national error rate calculation in the event that Congress adopts legislation which mandates the use of cost reimbursement for infusion services. The complete text of HCFA's response is included as Appendix A.

INTRODUCTION

BACKGROUND

Infusion therapy is growing as an alternative to a wide variety of medical and post-surgical conditions.

Infusion therapy is administered for:

- pain management,
- chemotherapy,
- dehydration,
- feeding, and
- antibiotic treatment.

Frequently SNFs contract with infusion therapy suppliers to purchase infusion services "under arrangement." The infusion therapy suppliers generally provide the drugs, solutions, supplies, and equipment. Some infusion therapy suppliers provide the nursing services to administer the intravenous (IV) solutions at the SNFs.

Prior to the implementation of PPS, the infusion supplier submitted invoices to the SNF for Medicare infusion therapy services. The SNF, in turn, filed a claim with the Medicare fiscal intermediary for these services. The infusion therapy supplier's invoice represented the SNF's cost for the services. The SNF's Medicare claim included the invoiced amount plus an additional charge to cover the SNF's overhead.

From 1995 through 1998, HCFA records showed that SNFs charged Medicare more than $1.4 billion for infusion services. These charges included the costs billed by the infusion suppliers and the additional administrative and general costs billed by the SNFs.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objective

The audit objective was to determine if infusion therapy services provided by some infusion suppliers to Medicare-reimbursed SNFs were reasonably priced, medically necessary, and classified correctly on the cost reports.

Scope

We performed detailed testing of charges associated with infusion drugs and supplies provided by three infusion companies. To quantify the impact to Medicare, we reviewed

claims submitted by 22 SNFs that used various infusion therapy suppliers. The vast majority of infusion services were provided by two of the three infusion therapy suppliers reviewed in this audit. For a chain of 13 SNFs, we selected a statistical sample of 100 claims submitted during 1995 through 1998 out of a universe of 1,133 infusion therapy claims. The 100 infusion claims were tested to determine whether the prices were reasonable, the services were medically necessary, and costs were classified correctly on the cost reports.

In addition, Mutual of Omaha, a Medicare fiscal intermediary, and HCFA medical review staff performed a medical review of another 154 claims from this chain. Finally, Mutual of Omaha performed a medical review of an additional 208 claims from 9 other nursing homes.

We did not review the overall internal control structure of the selected nursing homes. The internal control review was limited to obtaining an understanding of the nursing homes' billing processes. Our tests of internal controls were accomplished through substantive testing.

Methodology

To determine whether services were medically necessary, we obtained the medical records from the facilities and forwarded the records to medical professionals for medical reviews. The medical reviews were performed by physicians with the Texas Medical Foundation, the Medicare peer review organization (PRO) for Texas; nurses at Mutual of Omaha; and a nurse from HCFA. To determine whether the SNFs paid reasonable prices for the infusion services, we obtained pricing information and interviewed officials from 10 infusion companies in Texas to determine a prevailing price. To determine whether infusion services were classified correctly, we reviewed the infusion invoices, interviewed the relevant billing officials at the nursing homes, and traced the invoices to each nursing home's general ledger and cost report.

Field work was performed at four nursing homes in Texas; two infusion supply companies in Texas; Mutual of Omaha corporate headquarters in Omaha, Nebraska; and the OIG Dallas field office. The audit was performed in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

Excessive Prices Were Paid

Infusion therapy suppliers charged SNFs excessive prices for infusion therapy services. The SNFs, in turn, passed these excessive costs on to Medicare under Medicare's retrospective, reasonable cost-based system. Although Medicare imposed a prudent buyer requirement on

the SNFs,[1] there was little incentive for a SNF to obtain the best price. Furthermore, it was resource intensive for the fiscal intermediary to establish the prevailing rate that a prudent buyer should have paid. Consequently, there was little assurance in the cost-based Medicare reimbursement system that an excessive cost would be adjusted downward to reflect the prevailing rate. As a result, Medicare paid substantially more than market rates for infusion services.

Based on a survey of infusion suppliers in Texas, we found that charges for infusion drugs varied widely, from as little as Average Wholesale Price (AWP), which is generally considered a reference price for drugs by the pharmaceutical industry, to more than 20 times AWP. Overall, infusion suppliers in Texas historically charged one to four times AWP for infusion drugs.[2]

The following examples illustrate the excessive prices that infusion suppliers charged SNFs for infusion drugs:

Drug	*Cost to SNF*	*AWP*	*Percent Difference*
Timetin	$155.49	$14.75	1054%
Bactrim	$197.86	$16.00	1237%
Cefotan	$152.57	$11.58	1318%
Vancomycin	$269.76	$15.60	1729%
Mefoxin	$127.24	$12.12	1050%

- One nursing home chain paid an infusion supplier $205 per liter of total parenteral nutrition (TPN) during 1995. The nursing home signed a new infusion contract with the supplier in 1996. After the new contract was executed, the nursing home paid the infusion supplier $1,180 per liter of TPN even though TPN was available from another Texas infusion supplier for $186 per liter. Upon the adoption of Medicare PPS, the infusion supplier lowered its price of TPN from $1,180 per liter to $90 per liter.

- The same infusion supplier charged SNFs more than $460 under the cost reimbursement system for three liters of sodium chloride for hydrating patients. The

[1]Section 2103 of the Provider Reimbursement Manual requires the provider to employ the prudent buyer concept. Specifically, the prudent buyer not only refuses to pay more than the going price for an item or service, but he/she also seeks to economize by minimizing cost. The intermediary excludes excess costs in determining allowable costs under Medicare.

[2]By comparison, Medicare Part B pays significantly less for drugs. Historically, under Medicare Part B, covered prescription drugs were reimbursed at AWP. As of January 1, 1998, Medicare Part B reimburses 95 percent of the AWP for covered prescription drugs.

cost per liter to the infusion supplier was $1.06, or $3.18 for the three liters. Under PPS, the infusion supplier lowered its charges to $15 ($5 per liter) for the same hydration solutions.

Under the cost reimbursement system, SNFs had little incentive to reduce costs. In fact, SNFs had an economic incentive to increase ancillary costs because Medicare reimbursed administrative and general costs to the SNFs based on the share of Medicare expenses incurred by the facilities. Consequently, by paying more for ancillary services, the facilities received additional administrative and general cost reimbursement from Medicare. In addition, suppliers were making such tremendous profits on these services that there was a strong incentive to provide additional services, even though the services were not medically necessary.

Medically Unnecessary Services Were Provided

Infusion therapy suppliers provided infusion therapy services to SNF residents that were not medically necessary. A review by medical professionals of 462 infusion therapy claims submitted by 22 SNFs disclosed that $4.8 million out of $9 million in charges were denied (53 percent).

Because Medicare paid substantially more than the market rate for these infusion therapy services, there was a strong incentive to supply excessive and unnecessary services. Infusion suppliers took a direct interest in patient care. In fact, nurses from the infusion supplier routinely assessed patients when they were admitted to the SNF, and recommended infusion therapy services. As a result, according to the PRO physicians, unnecessary infusion therapy services were performed which put nursing home patients at risk of increased medical problems, including infection and electrolyte imbalance. In addition, infusion therapy services are invasive procedures which are painful and, when unnecessary, reduce the quality of a patient's life. Finally, Medicare compensated SNFs for these types of claims that should not have been paid.

Title XVIII of the Social Security Act (the Act), section 1862(a)(1)(A), states that no payment may be made under Part A or Part B of Medicare for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

To illustrate, an 80-year-old skilled nursing patient was transferred from a SNF to a hospital. While in the hospital, the patient had a gastronomy tube placement to assist in eating. When the patient returned to the SNF, he was started on tube feedings. Even though he was tolerating the tube feedings well, a nurse who worked for the infusion supplier evaluated the patient for intravenous feeding within days of his return from the hospital. Based on her patient evaluation, the infusion nurse contacted the facility doctor and recommended that infusion services be started. The facility doctor authorized the IV feedings. The PRO

physician who performed a medical review of the claim determined that the IV feedings were not necessary because the patient had a gastronomy tube and was taking the gastronomy tube feedings without difficulty. The PRO physician also concluded that this patient's health was placed at risk.

Costs Were Misclassified

The SNFs we reviewed misclassified infusion costs on their cost reports. Specifically, charges for nursing services and charges for equipment, such as infusion pumps and poles, were classified as ancillary instead of routine, despite a fiscal intermediary's determination that the costs should be treated as routine. Infusion costs were misclassified because the infusion suppliers misrepresented items on the invoices and provided misinformation to the SNFs about the treatment of the costs.

Before the adoption of PPS, the reasonable cost of ancillary services and capital-related expenses were paid in full. Routine operating costs were paid on a reasonable cost basis as well; however, they were also subject to per diem limits. Sections 1861(v)(1)(A) and 1888 of the Act authorized the Secretary to set limits on the allowable routine costs incurred by a SNF.

The Provider Reimbursement Manual, HCFA Publication 15-1, sections 2203.1 and 2203.2, defines ancillary and routine costs for SNFs. Drugs are defined as ancillary, whereas reusable equipment, such as infusion pumps and poles, are defined as routine. The Provider Reimbursement Manual does not explicitly state whether infusion nursing costs are routine or ancillary. However, for items not explicitly classified, the Provider Reimbursement Manual requires the provider to comply with the prevailing practice in the geographic area. In 1994, Mutual of Omaha, a Medicare fiscal intermediary, performed a survey and determined that the prevailing practice in Texas was for SNFs to classify infusion nursing costs as routine. Mutual of Omaha issued a Medicare newsletter to all its providers stating that nursing costs associated with infusion services were routine.

To market infusion services, the three infusion suppliers engaged in practices that permitted SNFs to bill nursing services as ancillary costs, contrary to the Medicare newsletter. In addition, the infusion suppliers attempted to conceal the routine costs from the fiscal intermediary by misrepresenting invoices that they submitted to the SNFs.

- One infusion supplier provided a cost report consultant as part of its standard infusion services contract. The cost report consultant advised SNFs that all infusion services, including nursing services, were ancillary.

- The same infusion supplier began charging $25 per nursing visit for its SNFs that filed claims with Mutual of Omaha as a result of Mutual of Omaha's newsletter. However, the supplier paid its nurses more than $25 per visit. The shortfall was

made up by increasing the price of the infusion drugs that the SNF was charged. The infusion supplier did not charge for the nursing visits for its SNFs that filed claims with Blue Cross of Texas, another Medicare fiscal intermediary. These SNFs were charged even higher prices for drugs.

- Marketing representatives from an infusion supplier informed prospective SNF clients that nursing services were free. The supplier was able to provide the "free" services by increasing the price of the infusion drugs.

- Another infusion supplier did not charge SNFs for nursing services. To cover the cost of the nurse, this supplier increased the price of infusion drugs by $110 per bag.

- Finally, another infusion supplier had a policy to charge $50 per nursing visit. However, the invoices that this supplier provided to SNFs disguised the $50 nursing charges as "ancillary supplies."

As a result of the misrepresentations, Medicare reimbursed the SNFs for costs that should have been classified as routine costs. These costs should have been subject to the routine cost limits. Instead, by claiming them as ancillary costs, there was no cost limit.

Monetary Impact of Unnecessary and Excessively Priced Infusion Services

Of the $9 million in audited claims submitted by 22 SNFs, $4.8 million in claims were not medically necessary. An additional $332,000 in payments that were found to be medically necessary were questioned because the prices exceeded the prevailing rate. Finally, another $158,000 was questioned because routine costs were misclassified on the cost report as ancillary costs.

One of the three infusion suppliers we reviewed has entered into a $10 million settlement agreement to resolve its civil liability under the False Claims Act and Civil Monetary Penalties Law which involved delivery of infusion services in Texas and in other States. The other infusion suppliers and many nursing homes are the subjects of additional audits and investigations by the OIG, the fiscal intermediary, and/or the Federal Bureau of Investigation.

Adoption of PPS

Section 4432(a) of the BBA required implementation of a Medicare PPS for SNFs. In 1998, HCFA implemented PPS for SNFs for cost reporting periods beginning on or after July 1, 1998. The PPS rates were based on mean SNF costs for the cost reporting periods beginning in FY 1995.

Since the adoption of PPS, concerns have been raised that reimbursement levels for high-cost services, including infusion therapy, are too low. Consequently, quality of care may be compromised. Various alternatives for changing PPS rates are being discussed, including establishing infusion therapy as a "carve-out" service. Under this approach, all costs associated with the service would be reimbursed similar to the Medicare SNF reimbursement system in place before 1998. Other alternatives include pending legislation which would increase the PPS rates for certain high-cost services, including infusion therapy. Another proposal is to change the base year for establishing PPS rates from 1995 to 1997. Underpinning these alternatives is an assertion that the 1995 base year does not accurately represent increases in patient acuity that occurred at SNFs during 1996 through 1998. While infusion therapy charges did increase significantly after 1995, these increases cannot be attributed solely to increased acuity levels. In fact, we are concerned that increases in infusion therapy charges over this period may have been dramatically impacted by the abusive practices described in this audit report.

CONCLUSION AND RECOMMENDATIONS

While our audit did not focus on the accuracy of the PPS rates for infusion therapy, we want to bring the results of our audit work to your attention should HCFA decide to change the reimbursement rates. We believe the adoption of PPS should help to correct the problem of SNFs and suppliers engaging in abusive billing schemes to increase Medicare reimbursements. However, PPS rates that do not reasonably reflect the SNFs' costs of providing services could still result in financial windfall to the SNFs. Under PPS, patients may still be subjected to unnecessary services. This could occur if unnecessary infusion therapy services were performed which may increase the patient's classification of services to a higher payment level within the PPS structure. Thus, more patients may be harmed by unnecessary infusion therapy.

We are concerned that HCFA may not have made adjustments for unallowable infusion therapy costs prior to the implementation of PPS.[3] The three infusion suppliers audited accounted for at least $138 million, or approximately 20 percent of all infusion therapy costs incurred by Medicare nationwide during 1995 through 1998.[4] Because the infusion therapy suppliers employed the same billing practices with hundreds of other SNFs in several States, we are concerned that additional unallowable costs were paid by Medicare

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[3]The issue of improper payments being included in the SNF PPS base year period costs was previously reported in our report entitled, "Review of the Health Care Financing Administration's Development of a Prospective Payment System for Skilled Nursing Facilities" (Report A-14-98-00350 dated July 1998).

[4]Between 1995 and 1998, SNFs charged Medicare a total of $1.4 billion for infusion therapy services. When SNFs billed Medicare for ancillary services, the SNFs would markup the direct costs they incurred to establish the Medicare charge. Generally, the markup was 100 percent of the direct costs. Accordingly, direct costs associated with infusion therapy services were about $700 million. The $138 million billed to SNFs by the three infusion therapy suppliers thus equates to about 20 percent of the total direct costs.

during 1995 through 1998. We also have concerns that these abusive practices may have resulted in inflated base year costs upon which the PPS rates were based. Furthermore, we believe reimbursement levels for infusion therapy that are too high affect quality of care due to overutilization, just as low reimbursement affects quality of care through underutilization. Therefore, before the PPS rates for infusion therapy are modified, we believe that the unallowable costs identified in this report should be seriously considered.

Accordingly, we recommend that HCFA:

- consider the impact of improper payments for infusion therapy services before making any refinements or updates to the SNF PPS rates. In addition, if legislative changes are adopted which mandate the use of cost reimbursement for infusion services, work with the OIG to quantify a possible national error rate for infusion therapy services;

- identify and recover overpayments which were made to SNFs for unnecessary and overpriced infusion services prior to the adoption of PPS; and

- direct its contractors to perform medical reviews of selected SNF patients to ensure that patients are receiving appropriate levels of infusion therapy.

HCFA COMMENTS AND OIG RESPONSE

In response to our draft report, HCFA generally agreed with our recommendations. In response to part of one recommendation, HCFA raised concerns about the benefit of establishing a national error rate for a set of services that is bundled with other sets of services into a single per diem rate under PPS. To take into account HCFA's comments, we changed our report to recommend a national error rate calculation in the event that Congress adopts legislation which mandate the use of cost reimbursement for infusion services. The complete text of HCFA's response is included as Appendix A.

DEPARTMENT OF HEALTH & HUMAN SERVICES

DATE: OCT 27 1999

TO: June Gibbs Brown
Inspector General

FROM: Michael M. Hash
Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Infusion Therapy in Skilled Nursing Facilities," (A-06-99-00058)

Thank you for the opportunity to review the above-subject report that examines infusion therapy services provided to Medicare-reimbursed skilled nursing facilities (SNFs) prior to the implementation of the Prospective Payment System (PPS).

The OIG found that all three of the infusion suppliers reviewed charged SNFs excessive prices for infusion therapy, provided unnecessary infusion services to SNF patients, and improperly billed SNFs for nursing services that the SNFs, in turn, misclassified on the Medicare cost reports. The findings raise concerns that these abusive practices may have resulted in inflated base year costs upon which the PPS rates were based.

The report makes convincing case that, in the past, medically unnecessary infusion therapy services were furnished to the extent that they became a threat to patient safety. We agree with the OIG that medically unnecessary infusion services could lead to patients being harmed. The health and safety of our beneficiaries is a paramount concern of the agency.

The report demonstrates that problems of over utilization are common in a cost reimbursement system. In recognition of the vulnerabilities inherent in such a system, the Congress required the Health Care Financing Administration (HCFA) to implement a PPS for SNFs. HCFA began to implement the new PPS on July 1, 1998, and all Medicare-participating SNFs were paid under this system before July 1, 1999.

Taken by itself, the PPS may still encourage overuse of services. For this reason, we issued new medical-review guidelines to our fiscal intermediaries to assess whether services were reasonable and necessary as they determine whether a payment was made properly. In addition, HCFA recently published new medical review guidelines regarding Medicare's new SNF PPS, and we plan to hold related training in the current fiscal year.

Because we have instituted a new payment system which departs quite significantly from the old, cost reimbursement payment system, we believe it is essential to gain a more complete understanding, as soon as possible, of the nature and distribution of any payment errors being made. Hence, we have instructed our contractors to concentrate their efforts on random review of claims, and plan to use those results to focus additional efforts.

If we find problems in therapy use or other areas during these random reviews, we will move quickly to instruct contractors to focus on those problem areas. This will ensure that we devote appropriate resources to therapy use, as the report recommends.

Our specific comments on the report recommendations follow:

OIG Recommendation
HCFA should consider the impact of improper payments for infusion therapy services before making any refinements or updates to the PPS rates.

HCFA Response
We concur. While the report utilizes a relatively small sample, it nevertheless raised important questions concerning the appropriateness of the delivery and historical pricing of infusion therapy services in SNFs. It will be important for HCFA to consider the issues raised as work on refinements to the SNF PPS case mix adjustment progresses. In fact, HCFA is using standardized measures of pricing in its research on the refinements to the PPS.

OIG Recommendation
HCFA should work with the OIG and the fiscal intermediaries and Medicare Integrity Program contractors to quantify a possible national error rate for infusion therapy services, and to identify and recover overpayments which were made to SNFs for unnecessary and overpriced infusion services prior to the adoption of PPS.

HCFA Response
We concur in part. We will recover overpayments where appropriate. However, regarding quantifying a possible national error rate for infusion therapy services, establishing and tracking an error rate for a particular service (such as infusion therapy) would not be beneficial from a payment perspective. Each SNF PPS case-mix category (i.e., Resource Utilization Group) bundles all applicable services furnished to a beneficiary into a single per diem rate. As a result, all services furnished in a group are bundled into SNF prospective payment categories and all services are reviewed for appropriate utilization and coverage. To establish a national payment error rate and

tracking system for the particular service that is included within a payment category (and if denied may not adjust a payment level) would not significantly generate a medical review benefit.

OIG Recommendation

HCFA should direct its contractors to perform medical reviews of selected SNF patients to ensure that patients are receiving appropriate levels of infusion therapy.

HCFA Comment

We concur. Since May 1999 we have directed our contractors to perform medical review of SNF PPS claims on a random basis (Transmittal NO. 99-20, "Payment Safeguard Review of SNF Prospective Payment Bills"). We, therefore, believe that all facilities will be at risk of being selected for review, and that those patients receiving infusion therapy will be reviewed for appropriate utilization levels.

R-1

CONFIDENTIAL

Etopophos®

(NDC 0015 - 3404 - 20)

(etoposide phosphate) for Injection

Launch Plan

Anticipated Launch: September/October 1995

BRAND POSITIONING STATEMENT:

Etopophos® (etoposide phosphate) for Injection is a water-soluble prodrug of etoposide which displays identical activity to the parent compound. The solubility of Etopophos in aqueous solutions provides distinct benefits over etoposide. Etopophos can be infused over as few as 5 minutes without causing hypotension and can be admixed in concentrations as high as 20 mg/mL. Etopophos represents a significant advance in the clinical and practical utility of podophyllotoxin derivatives.

"5/20"

(Five minute infusions/20 mg/mL concentration)

Larry J. Lunak
September 6, 1995

Executive Summary

In 1983, Bristol-Myers introduced VePesid® (etoposide) for Injection to the oncology community. In the 10 years in which the brand enjoyed domestic exclusivity, VePesid grew to become the highest selling cytotoxic in the United States. The year 1993 marked the apex of VePesid injectable growth with net sales in excess of $188 MM. With a strong clinical database and over a decade of experience, etoposide ranks as one of the most valuable agents available to today's clinicians in the fight against cancer.

The year 1987 saw the introduction of VePesid® (etoposide) capsules. Providing etoposide in a convenient oral form, VePesid capsules allowed clinicians to take advantage of a growing body of clinical data that, by 1990, suggested chronic, low dose exposure to etoposide provides a measurable benefit over traditional three day intravenous dosing. In 1993, VePesid capsules produced net sales of approximately $20 MM. Fueled in part by the Medicare Cancer Coverage Improvement Act, 1994 net sales of VePesid Capsules grew over $5 MM to $25.6 MM -- a 27 percent growth over 1993.

Together, VePesid capsules and injectable reached total net sales of $208 MM in 1993. Aside from setting the brand and divisional sales record in that year, 1993 also marked two very important changes in the VePesid Market -- the introduction of three new VePesid vial sizes (150 mg, 500 mg, and 1 gram) and, more importantly, the loss of the compound's exclusivity protection on November 11, 1993.

Although actual generic competition did not become a reality until February 14 of 1994, it had been anticipated as early as November of 1993. In expectation of such competition, BMOD instituted an aggressive partnering program with individual hospitals and Group Purchasing Organizations (GPOs) to support continued brand loyalty in the face of generic competition. Through the seemingly tireless work of the Bristol Laboratories Oncology Products sales force, over 1,500 hospitals and nearly 70 percent of all oncologists' office practices enrolled in BMOD's VePesid programs.

As a result of generic competition, final net sales for VePesid for Injection fell to $108.4 MM in 1994. Although at first glance this $72 MM drop seems dramatic, the $108.4 MM figure is quite respectable in light of market conditions. Facing nearly a full year of competition, the brand lost only 42 percent of its 1993 net sales. This loss was nearly evenly split between lost units (approximately 20 percent) and reduced net sales price (also approximately 20 percent). In addition, hospital groups having signed VePesid contracts

during 1993 received as much as 1.2 months of VePesid during the last week of December. Contractees signed during 1994 also received equivalent amounts of free VePesid. As a result, net sales figures actually underestimate the amount of VePesid successfully channeled into the marketplace in 1994.

Despite its overwhelming acceptance by the oncology community, etoposide as a clinical compound has several drawbacks. The molecule has a very **low water solubility** and must be produced in a non-aqueous form for parenteral administration. To achieve a pharmaceutically elegant product, etoposide **must be formulated with a variety of excipients** (citric acid, ethanol, benzyl alcohol, modified polysorbate 80, and polyethylene glycol). As a consequence of its formulation, VePesid must be administered over 30 to 60 minutes to decrease the patient's risk of experiencing excipient-induced hypotension. As a result of etoposide's low water solubility, VePesid admixtures **cannot exceed 0.2 to 0.4 mg/mL** without running the risk of the product precipitating. Also, the excipients used in the manufacture of etoposide injection produce a **physio/chemical reaction with acrylic and ABS polymers** which precludes the product's use with many chemo safety devices.

Etopophos® (*etoposide phosphate*) for Injection eliminates many of these concerns. A phosphate ester of etoposide, Etopophos is readily water soluble. Being highly water soluble, Etopophos can be manufactured as a *lyophilized powder,* avoiding the use of the various excipients which impart many of the negative attributes of etoposide for injection. Thus, etoposide phosphate can be administered over as few as *five minutes,* can be admixed at concentrations as high as *20 mg/mL* (compared to a maximum concentration of only 0.4 mg/mL for etoposide), and the formulation will not interact with acrylic and ABS polymers often used in chemotherapy admixture safety devices.

Etoposide phosphate is a *pro-drug* of etoposide. Upon parenteral administration, etoposide phosphate is rapidly and completely cleaved by circulating plasma phosphatases to yield etoposide. Thus, Etopophos eliminates the vast majority of etoposide's formulation drawbacks while still providing identical pharmacokinetic/pharmacodynamic properties.

Providing etoposide in the form of a phosphate ester results in a larger molecular weight for the compound. In fact, etoposide's molecular weight is 13.6% higher than the parent compound. As a result, Etopophos will be presented in single-dose vials containing 113.6 mg of etoposide phosphate -- a dose equivalent to 100 mg of etoposide. Since the drug becomes -- for all practical purposes -- etoposide once administered each vial will be treated by the admixing professional as a 100 mg vial of etoposide.

Exclusivity for the compound is assured through 2007. However, therapeutic substitution

of VePesid® (etoposide) for Injection and its generic competitors will continue to negatively impact upon Etopophos. Etopophos' physio/chemical attributes will serve as powerful differentiating feanures which should favor brand selection. In fact, BMS market research has shown Etopophos can maintain a premium price in the etoposide market. However, it must be noted that this premium differential falls as the market price for generic etoposide falls.

The Etopophos New Drug Application (#20-457) was submitted to the FDA for consideration on June 28, 1994. During the Agency's 45-day filing meeting the application was deemed to be "fileable." In addition, since the Etopophos NDA does not go beyond indications currently existing for the parent compound, the Agency determined the application need not undergo review by the Oncology Drugs Advisory Committee (ODAC). Based upon these facts, the FDA's Division of Oncology Drug Products initially anticipated completing their review of the application by year end, 1994. However, this did not come to pass. **Approval is now anticipated in an August to September 1995 timeframe.**

Upon launch, positioning strategy will stress the clinical equivalency of Etopophos to etoposide. The advantages of the brand (i.e., the ability to administer over as few as five minutes, the ability to admix at concentrations up to 20 mg/mL without risking precipitation, etc.) will be emphasized to justify the brand's premium price. Lastly, the financial advantages of conversion from etoposide to Etopophos will be stressed.

Appendix I. outlines a comparison of Etopophos and etoposide. This comparison and the brand positioning statement appearing on the cover of this plan represent the main thrust of the positioning strategy.

2. **Cannibalization of VePesid® (etoposide) for injection Business**

It is anticipated that the availability of Etopophos will result in the cannibalization of a portion of the existing VePesid and generic etoposide business. This is a logical assumption in light of the "saturated" etoposide market which has existed since the late 1980's. If correctly priced, the advantageous profile of Etopophos should result in a substantial shift in etoposide purchasing patterns toward Etopophos with the brand "cannibalizing" 25 to 30 percent of sales within the first 12 months.

How can BMSO best position Etopophos to cannibalize both VePesid injectable and regain share from its generic competitors?

3. **Pricing Concerns**

The launch of Etopophos represents the introduction of a premium product into a saturated and increasingly price-sensitive market. Since the advent of generic competition, the VePesid® (etoposide) for injection average selling price has declined by over 33 percent ($69 versus $109 per 100 mg vial) as of May 1, 1995. Future erosion is expected in light of multiple etoposide approvals expected throughout 1995.

The Etopophos product profile is significantly superior to that of etoposide for injection and is expected to support as much as a 20 percent price premium over VePesid injectable and its generic competitor(s). Market Research indicates, however, that the amount of premium the market will bear diminishes as the generic price erodes. As a result, at anticipated levels of $ 65.00/100 mg etoposide, Etopophos may support only a 10 to 15 percent premium. Once established, Etopophos may be able take advantage of the compound's superiority and maintain its pricing despite continued erosion of the VePesid/generic market.

In light of the delay in product approval and the expected rapid decline in market price due to multiple generic competitors, a decision may need to be made as to whether the brand is better served by attempting to be price competitive (with a premium) or to establish a higher price for the brand and allow it to fill a niche market where its advantages are best employed. Consideration of the latter option will become increasingly important if Agency approval is significantly delayed.

How can BMSO best implement a pricing strategy for Etopophos to ensure the brand maintains its introductory price in the face of further declines in market etoposide pricing and still maintain a market share of 30?

4. Physician Pricing Incentives

Currently, physician practices can take advantage of the growing disparity between VePesid's list price (and, subsequently, the Average Wholesale Price [AWP]) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physicians' financial incentive for selecting the brand is largely diminished.

To provide adequate financial incentive for the use of Etopophos, the following strategies could be employed:

1. Reduction of the VePesid AWP. Under this option, the list price and/or AWP for VePesid would be reduced from its current level to the highest bid price currently in the marketplace.

2. Establish a premium list price for Etopophos (etoposide phosphate) for injection. A list price of $120.54 would represent a 15% premium over the current VePesid (etoposide) for injection MD direct list price of $104.82, while $125.57 would represent 115% of the wholesale list price of $109.19.

   Volume based conversion discounts would be extended to:

   - Physician Practices (through BMOTN)
   - Hospitals (through GPO Partnerships)
   - Non-GPO Hospitals (through competitive bidding)
   - All other channels of trade (also through competitive bidding)

How can BMSO best price and discount Etopophos to negate any financial dis-incentives when compared to current reimbursement levels for VePesid and the generic etoposides? How can such a program be instituted to result in an average selling price of $75.00 per 100 mg equivalent Etopophos vial?

5. Lack of Market-Driven Clinical Data

Upon launch, relatively little efficacy data will be available for Etopophos® (etoposide phosphate) for injection. This is not a great concern since the compound

HOSPITAL PHARMACIST REPORT

UNDER ATTACK

VANCOMYCIN-RESISTANT *S. AUREUS* HITS U.S. SHORES

The United States confirms isolates of *S. aureus* with diminished susceptibility to vancomycin

R-2

The widespread, and often unwarranted, use of antimicrobial agents, particularly vancomycin is a major contributing factor in the emergence of *S. aureus* with diminished susceptibility to vancomycin. Both patients had recent prolonged exposure to vancomycin. Studies show that as many as 60% of vancomycin prescriptions in hospitals are inconsistent with CDC recommendations. Published in the MMWR, detailed recommendations for preventing and controlling *S. aureus* with diminished susceptibility to vancomycin emphasize strict adherence to contact isolation precautions and other recommended infection control practices, judicious use of vancomycin, and active surveillance for *S. aureus* with diminished susceptibility to vancomycin.

PROD. MFR	NDC	AWP	DP	OBC

VANCOMYCIN HYDROCHLORIDE

(Abbott Hosp)

R-3

PDI, IJ (ADD-VANTAGE)

500 mg, 10s ea	00074-6534-01	108.78	
(FLIPTOP VIAL)			
500 mg, 10s ea	00074-4332-01	302.34	AP
(ADD-VANTAGE)			
1 gm, 10s ea	00074-6535-01	217.55	
(FLIPTOP VIAL)			
1 gm, 10s ea	00074-6533-01	604.44	AP
(BULK VIAL)			
5 gm, ea	00074-6509-01	135.99	AP

VANCOMYCIN

500mg $4.20

1gm $8.40

FROM FLORIDA INFUSION 1995 CATALOG

R-4

PROD/MFR	NDC	AWP	DP	OBC

VANCOMYCIN HYDROCHLORIDE

(Abbott Hosp)

PDI, IJ (ADD-VANTAGE)

500 mg, 10s ea	**00074-6534-01**	113.17	**AP**
(VIAL, FLIPTOP)			
500 mg, 10s ea	**00074-4332-01**	314.45	**AP**
(ADD-VANTAGE)			
1 gm, 10s ea	**00074-6535-01**	226.22	**AP**
(VIAL, FLIPTOP)			
1 gm, 10s ea	**00074-6533-01**	628.66	**AP**
(BULK VIAL)			
5 gm, ea	**00074-6509-01**	141.43	**AP**

R-5

FROM FLORIDA
INFUSION
1996
CATALOG

R-6

VANCOMYCIN
500mg $3.95
1gm $7.95

PROD MFR	NDC	AWP	DP	OBC
VANCOMYCIN HYDROCHLORIDE				
(Abbott Hosp)				
PDI, IJ (ADD-VANTAGE)				
500 mg, 10s ea	00074-6534-01	137.63	115.90	AP
(VIAL, FLIPTOP)				
500 mg, 10s ea	00074-4332-01	382.14	321.80	AP
(ADD-VANTAGE)				
1 gm, 10s ea	00074-6535-01	274.91	231.50	AP
(VIAL, FLIPTOP)				
1 gm, 10s ea	00074-6533-01	764.16	643.50	AP
(BULK VIAL)				
5 gm, ea	00074-6509-01	171.90	144.76	AP

R-7

09/10/01 M c K e s s o n ECONOLINK System
22:30 Facility: VENA CARE
Range: From - 00074-6533-01 Selected By: NDC Code
Thru - 00074-6533-02 Sorted By: NDC Code

:scription: VANCOMY FTV 1GM ABB 10
Economost #: 2505626 Subst Econo #:
Local #: Local Dept:
Generic: 41281 VANCOMYCIN HCL Mica Dept: DA
Therapeutic: 081228 MISCELLANEOUS ANTIBIOTICS Form: VIAL
NDC: 00074-6533-01 Mfg Unit: UNIT
UPC: 3-00746-53301 Strength: 1G
Mfg Name: ABBOTT LABORATORIES HOSP Sched: 6
Alt Source: Std Ord Min: 001
Alternate ID: Size: 10.00
AWP: $177.25 Order Unit: EA
AWP Last Updt: 06/19/01 Case Qty: 00005
REG Price: $151.02 Qual Qty: 0 Price CD:
" Start Date: 00/00/00 End Date: 00/00/00 Last Update: 04/20/00
CNTR/SPCL Price: $43.67 Qual Qty: 1 Price CD: E
" Start Date: 07/01/01 End Date: 06/30/02 Last Update: 08/09/01
Retail Price: .00 Reg Code:
Retail Type: Reg Price:
Rtl Base Cost: .00 A.W.P.:
National Cost: .00 Profit %: .00
Sugg Retail: .00 Label Cnt:
Zone Cust: Last Maint: 00/00/00
Reorder Quantity: Source Supply: 0000
Reorder Point: .00 Inventory Cnts: .000
Velocity Ind: Physical Loc:

EXAMPLES OF
EXCESSIVE REIMBURSEMENTS FOR PHARMACEUTICALS BY
LOUISIANA MEDICAID PHARMACY PROGRAM

COMPANY	DRUG	NDC #	HCPCS CODE	LOWEST PRICE OIG REPORT *	AVERAGE MEDICARE ALLOWED OIG REPORT *	LOUISIANA MEDICAID REIMBURSEMENT **
Elkins-Sinn	Leucovorin 50 mg	00641-2369-41	J0640	$ 2.39	$ 21.70	$ 50.34
Chiron	Etoposide 100 mg/5 ml	53905-0291-01	J9182	$37.06	$137.57	$125.30
Abbott	Vancomycin HCL 500 mg	00074-4332-01	J3370	$ 3.45	$ 9.44	$ 30.43
Gensia	Doxorubicin HCL 10 mg/5 ml	00703-5043-03	J9000	$10.87	$ 44.19	$ 39.78
Gensia	Doxorubicin HCL 50 mg/25 ml	00703-5046-01	J9010	$54.00	$207.12	$198.91
Baxter Biotech	Immune Globulin 500 mg	00944-2620-01	J1561	$12.50	$ 42.21	$ 49.15
SmithKline	Granisetron HCL 1 mg/1 ml	00029-4149-01	J1625	$122.90	$170.02	$158.77
Glaxo/Cerenex	Ondansetron HCL 2 mg/ml 20 ml	00173-0442-00	J2405	$156.80 ***	$243.20 ***	$218.74 ***

* Lowest prices and Average Medicare Allowed Amounts excerpted from Appendix B, page B-3, Office of the Inspector General Report "Excessive Medicare Payments for Prescription Drugs" (December 1997, OEI-03-97-00290)

** Louisiana Medicaid reimbursements obtained from Louisiana Bureau of Health Services Financing Medical Assistance Program (504) 342-3891

***Reflects Prices for a 40 mg vial

51

Bristol-Myers Cefadroxil 500mg (bottle of 100)
NDC# 59772-7271-04
AWP = $305.00
HCFA Federal Upper Limit ("FUL") = $276.72
Ven-A-Care Net Invoice Cost = $82.90

S-2

State	Medicaid Reimbursement (Does not include dispensing fee)	Spread
Louisiana	$274.50	$191.60
Pennsylvania	$274.50	$191.60
Florida	$261.08	$178.18
Michigan	$205.00 State MAC	$122.10
Texas	$118.64 State MAC	$35.74
Ohio	$99.00 State MAC	$16.10

(IVAX's Cefadroxil now available for $47.48)

THE WALL STREET JOURNAL.

February 7, 2001

Facing an Impending Budget Crunch, States Seek to Curb Medicaid Costs

By ANDREW CAFFREY
Staff Reporter of THE WALL STREET JOURNAL

MEDICAID is looking like a budget buster again.

The mammoth health program that provides health and nursing-home care to low-income and elderly residents is being hit by an explosion in prescription-drug use and a surge in caseloads -- just as states are beginning to struggle with fast-declining revenues. As a result, states are deploying multiple strategies to wring as much as several hundred million dollars in savings from their Medicaid programs.

States, however, aren't seeking to cut the politically popular benefits; in fact, they are looking for ways to maintain -- and even expand -- services. Instead, states are looking for more concessions from health-care providers.

The pharmaceutical industry is the main target, because states say the drug-cost component of Medicaid is rising at more than 20% annually. In spending proposals submitted to Legislatures in Missouri, Maine, Florida and others, governors are seeking bigger discounts from manufacturers and restricted access to expensive brand-name drugs. In other states, including New Jersey and Connecticut, governors are proposing that local pharmacies be required to lower their prices.

Meantime, nursing homes and hospitals that treat Medicaid patients are another target. Proposed budgets in states such as New York, Ohio and Indiana contain provisions to cut reimbursement rates.

Sharing the Pain

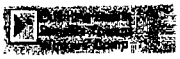
Total state Medicaid costs are projected to rise 8% to 12% for the

Help
New Features
E-mail Center
Your Account
Contact Us
WSJ.com Gifts
Glossary
Special Reports
Weather

STOCK QUOTES

Free WSJ.com Sites:
Books
Careers
College
Homes
Online Investing
Opinion

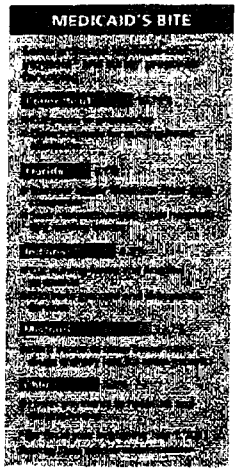
fiscal year beginning July 1, while tax revenues in some states are expected to grow by only 3% to 4.5%. And many states are moving to expand coverage to include more uninsured Americans. Connecticut has a new program that is expected to cost $30 million to cover 18,000 working parents over the next fiscal year. Ohio is proposing to add nearly 5,000 new beds for disabled, mentally retarded and elderly nursing-home residents.



But with states loath to cut Medicaid benefits -- and concessions from providers likely to cover only part of the higher costs -- budget writers are looking elsewhere in state government to save money. "The rest of state government is dramatically impacted," says Timothy Keen, assistant budget director in Ohio, where Medicaid costs are projected to rise 7.7% for the fiscal year beginning July. Under Gov. Bob Taft's proposed budget, 27 state agencies would see funding cut from current levels. For instance, drug-and-alcohol addiction services would see a $2.5 million cut.

Wednesday in Connecticut, which faces nearly an 11% increase in Medicaid costs, Gov. John Rowland plans to announce a hiring freeze on all noncritical agencies in his spending plan for fiscal 2002. Marc Ryan, the state budget director, says Medicaid will account for $249 million, or 55% of the $450 million in new spending the administration seeks for next year's budget.

And in Missouri, "we've had to do perhaps the biggest core cuts to our agencies in years," says budget director Brian Long. In part because of Medicaid costs, the state won't fund increased costs for school transportation and special education, for example.



To be sure, states have access to other resources, such as funds from the tobacco-industry lawsuit, to indirectly ease pressures on Medicaid. Some 29 states are moving to exploit a loophole that allows them to recoup billions of dollars from the federal government for care at county-run medical facilities. States have several more years to tap into this pot of money, though the federal government is considering closing the loophole.

More Concessions

Still, the pressure is on to attack Medicaid costs themselves. Here's a closer look at some plans to pare those expenses:

- **Squeezing drug makers:** Five years ago, prescription drugs were 8% of Florida's Medicaid costs; next year they will be 19% of total spending, says state Medicaid director Bob Sharpe. He says higher drug costs account for 70% of the $1.5 billion increase in Medicaid expenses projected for next year.

Florida has perhaps the most ambitious state plan to wring concessions from drug makers. Gov. Jeb Bush proposes to save $100 million in state funds next year by forcing drug companies to increase the rebates they offer Medicaid programs, to 25% from 19%. Companies that don't comply would find their medicines on a restricted list that makes it harder for doctors to prescribe them, says Mr. Sharpe.

An industry trade group, Pharmaceutical Research and Manufacturers of America in Washington, D.C., says it will oppose the plan because it would set off a chain reaction among other states to demand similar deeper discounts.

- **Going to generics:** Missouri's proposed budget is one of

several seeking to hire consultants to examine such things as whether physicians are prescribing effective but cheap generic drugs. Maine's spending plan would mandate generic substitutes where possible and limit the number of doctors from whom a single patient can get a prescription.

- **Targeting druggists:** Nearly 20 states have adopted or are considering measures to require deeper discounts from pharmacies and cut the fees druggists get for filling prescriptions, says the National Association of Chain Drug Stores, an Alexandria, Va., trade group. But the group's general counsel, Larry Kocut, says targeting his members doesn't make sense. "If drug costs are rising, and we have no control over the utilization, cutting us doesn't really solve the problem," he says. Most states want to raise average discounts to 15% from 10% and cut pharmacists dispensing fees to, for example, $2 from $4. New Jersey's budget proposes only the larger discounts, and only from drug stores that fill more than 10,000 prescriptions a year.

- **Pressuring the providers:** Indiana has proposed cutting its reimbursements to hospitals and nursing homes by 5%. Those and other measures are part of a $61 million savings package Indiana officials proposed under pressure from state legislators who are concerned about a projected 9.2% rise in Medicaid next year and want more money for public education.

Nursing homes in Indiana say they couldn't afford a 5% cut. "I think we're at a desperation point," says Rodney McBride, vice president of the Bloomington Hospital and Health Care System in Indiana, which is closing one of its four nursing homes because it's losing money providing care to Medicaid patients.

The battle to curb Medicaid costs is likely to prompt many such complaints. "People will be very upset about our budget," says Connecticut's Mr. Ryan. "Frankly it's not as bad as we'll see in the future if medical-inflation trends continue as they are and if revenue trends continue down."

Write to Andrew Caffrey at andrew.caffrey@wsj.com

VEN-A-CARE
OF THE FLORIDA KEYS, INC.
A Home I.V. and Nutritional Service

933 FLEMING ST
KEY WEST, FLA. 330-
(305) 292-1635
FAX (305) 292-173

T-1

June 12, 1997

Dr. Bruce Vladeck
Administrator
Health Care Financing Administration
Department of Health and Human Services
200 Independence Blvd. S.W.
Hubert Humphrey Building Room 314G
Washington, D. C. 20201

RE: THE HEALTH CARE FINANCING ADMINISTRATION'S KNOWING SQUANDERING OF MORE THAN ONE BILLION DOLLARS OF MEDICARE FUNDS FOR PARENTERAL NUTRITION.

Dear Dr. Vladeck,

Ven-A-Care of the Florida Keys, Inc., "VAC", has for the past six years attempted to assist the Health Care Financing Administration, "HCFA", in limiting infusion and inhalation pharmaceutical reimbursements to the reasonable levels contemplated by United States laws and regulations.

One of the specific pharmaceutical products is Total Parenteral Nutrition, "TPN". TPN is covered under the Prosthetic Device Benefit of Part B of the Medicare Program. During the past six years, VAC's officers, directors and legal counsel have made countless telephone calls, written numerous letters, created numerous reports and made detailed presentations to HCFA and other responsible governmental officials detailing the grossly excessive, price gouging reimbursements that the Medicare Program is making for TPN. For years, VAC characterized these payments as being unwittingly made by HCFA. However, after six years of knowledge by HCFA and no discernable action concerning these grossly excessive reimbursements, these payments can no longer be characterized as unwitting.

Enclosed herewith you will find a toilet seat, together with a bag of TPN, HCPCS code B4199, that has been admixed with parenteral nutrition lipids 20%, HCPCS code B4186. The toilet seat is symbolic of the grossly excessive payments made a number of years ago by the Pentagon. To this day, Americans still remember the Pentagon's $400.00 toilet seats. Fortunately, for American taxpayers, the Pentagon only purchased a limited number of the infamous $400.00 toilet seats. Conversely, HCFA ,after six years of knowledge about the true costs for TPN and ancillary supplies continues to allow grossly excessive payments to be made. The bag of TPN enclosed herewith and the ancillary supplies and pump costs VAC a total of **$48.90 per day** , yet our Nation's Medicare Program which you administer continues to allow **$427.67 per day** for TPN (HCPCS codes B4199, B4186, B4224, B4220, B9006RR, and E0776RRXA).

Financial data obtained from the Part B Extract and Summary System "BESS" reports indicates that the Medicare Program has allowed approximately **$1.4 billion dollars** during the last six years for parenteral nutrition and ancillary supplies and pumps. Your agency's inability to act responsibly and take corrective action has cost our Nation's Medicare Program approximately **$1.176 billion dollars in excessive payments** during the past six years (computation equals VAC's cost plus a reasonable 40% profit margin). You should be ashamed of your agency's course of conduct particularly in light of the fact that the Medicare Program is now raising beneficiaries' Part B premiums and the Medicare Part A Program's financial solvency is in jeopardy.

We have elaborated in previous communications the fact that during the past six years Medicare's allowable for TPN has risen despite the fact that the cost in the private sector has fallen dramatically. The Medicare Program now pays two to three times the amounts that private insurers pay for TPN.

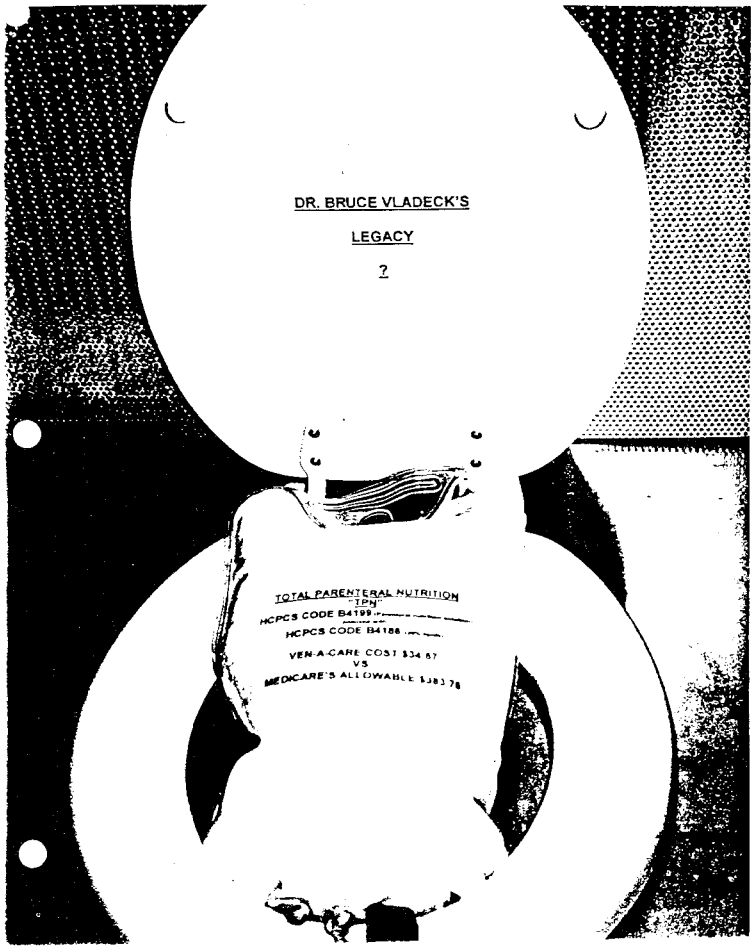
If you fail to heed our last cry for you and your agency to take responsible action, your legacy as the Administrator of HCFA may well be remembered as the Administrator responsible for purchasing Medicare's version of the infamous $400.00 toilet seats. We are aware that this letter is less than cordial. However, we hope that you will find our frankness and candor sobering and will finally take some immediate corrective action. Be advised that we are willing to wait no more than thirty days (30) from the date of this letter for you or your agency to send to us a copy of your plan outlining the corrective measures and timetable for implementation before VAC seeks to implement its own corrective plan.

Sincerely,

Zachary T. Bentley

T. Mark Jones

cc: minus toilet seat and TPN
HHS Secretary, Donna Shalala
Inspector General, June Gibbs Brown
Congressman Fortney "Pete" Stark
Teruni Rosengren, GAO
Michael Hertz, Esquire, United States Department of Justice
James Breen, Esquire, Wampler, Buchanan and Breen
Atlee Wampler III, Esquire, Wampler, Buchanan and Breen


DR. BRUCE VLADECK'S
LEGACY
?
TOTAL PARENTERAL NUTRITION
"TPN"
HCPCS CODE B4199
HCPCS CODE B4188
VEN-A-CARE COST $34.67
VS
MEDICARE'S ALLOWABLE $383.76

VEN-A-CARE
OF THE FLORIDA KEYS, INC.
A Home I.V. and Nutritional Service

933 FLEMING ST
KEY WEST, FLA. 330
(305) 292-1635
FAX (305) 292-17

T-2

August 13, 1997

Dr. Bruce Vladeck
Administrator
Health Care Financing Administration
Department of Health and Human Services
200 Independence Blvd. S.W.
Hubert Humphrey Building Room 314G
Washington, D.C. 20201

RE: THE HEALTH CARE FINANCING ADMINISTRATION'S KNOWING SQUANDERING OF TENS OF MILLIONS OF DOLLARS ANNUALLY IN PRECIOUS MEDICARE AND MEDICAID PROGRAM FUNDS BY FAILING TO ACT RESPONSIBLY BY STOPPING THE MEDICARE CARRIERS AND STATES' MEDICAID AGENCIES FROM PAYING PROVIDERS MORE FOR CERTAIN GENERIC DRUGS THAN THEIR EQUIVALENT BRANDS

Dear Dr. Vladeck,

We are again writing to you to provide you and your agency, the Health Care Financing Administration ("HCFA"), with the opportunity to act responsibly.

Approximately two years ago, we gave HCFA specific examples of pharmaceuticals whereby the Medicare and States' Medicaid programs were paying providers MORE FOR GENERIC DRUGS THEN THEIR EQUIVALENT BRANDS. Many examples showed that the State's Medicaid Programs were paying more then TWICE the amount for generic's then the equivalent brands. After two years of knowledge about this outrageous waste of the Programs funds, neither you nor HCFA have taken any discernable action. Be apprised that due to HCFA's inaction this problem has now expanded to include other drugs. YOUR ADMINISTRATION'S COURSE OF CONDUCT CONCERNING THIS MATTER IS IRRESPONSIBLE AND UNACCEPTABLE.

This type of irresponsible management and wasteful spending is deserving of a chapter in the popular book entitled The Death of Common Sense. Enclosed you will find three charts which compare reimbursements currently being made by the Medicare and States' Medicaid Programs for generic drugs versus their equivalent brands.

I realize that your tenure as HCFA's Administrator will soon end, however, if you fail to take immediate action concerning this matter, you will be remembered as the HCFA Administrator who knowingly allowed the Medicare Program to purchase the equivalent of $400.00 toilet seats (TPN) and for allowing the Medicare and States' Medicaid Programs to pay more for generic drugs than their equivalent brands.

Be advised that Abbott Labs has announced availability of a new generic acyclovir sodium for injection. As evidenced by our third chart , Abbott Labs published and/or caused to be published a price that is approximately 40% higher then the brand Zovirax thus causing the State s Medicaid Programs to pay significantly more for Abbott s generic than Glaxo-Wellcome's Brand Zovirax. As you may or may not be aware, acyclovir is an antiviral drug that is widely prescribed for persons who are inflicted with HIV diseases.

We sincerely hope that your Administration will immediately cease and desist facilitating the financial exploitation of the suffering of this nation s Medicare beneficiaries and Medicaid recipients.

Sincerely,

Zachary T. Bentley

T. Mark Jones

c.c. HHS Secretary, Donna Shalala
Inspector General, June Gibbs Brown
Congressman Fortney "Pete" Stark
Teruni Rosengren, GAO
Michael Hertz, Esquire, United States Department of Justice
James Breen, Esquire, Wampler, Buchanan and Breen
Atlee Wampler III, Esquire, Wampler, Buchanan and Breen

EXAMPLES OF THE MEDICARE PROGRAM PAYING PROVIDERS MORE FOR GENERIC DRUGS THAN THE BRANDS

BRAND				FLORIDA MEDICARE (GENERIC)		
COMPANY	DRUG	NDC	RED BOOK AWP	HCPCS	DRUG	1997 FLORIDA MEDICARE ALLOWABLE
Lilly	Vancocin 500mg	00002-1444-01	$ 7.80	J3370	Vacomycin 500 mg	$ 12.91
Bristol Myers	Kantrex 500 mg	00015-3502-20	$ 3.36	J1840	Kanamycin Sulfate 500 mg	$ 6.69
Glaxo Wellcome	Lanoxin 0.5 mg	00173-0260-10	$ 2.35	J1160	Digoxin 0.5 mg	$ 2.53
Roche	Fluorouracil 500 mg	00004-1977-01	$ 1.52	J9190	Fluorouracil 500 mg	$ 1.55
Bristol Myers	Vepesid 100 mg	00015-3095-20	$136.49	J9182	Etoposide 100 mg	$141.97

EXAMPLES OF STATES' MEDICAID PROGRAMS PAYING PROVIDER MORE FOR GENERIC DRUGS THAN THE BRANDS

BRAND					GENERIC			
COMPANY	DRUG	NDC	FLORIDA MEDICAID		COMPANY	DRUG	NDC	FLORIDA MEDICAID
Lilly	Vancocin 500 mg	00002-1444-01	$ 6.67680		Abbott	Vancomycin 500 mg	00074-4332-01	$ 30.85017
Lilly	Vancocin 500 mg	00002-1444-01	$ 6.67680		Fujisawa	Lyphocin 500 mg	00469-2210-30	$ 7.49000
Lilly	Vancocin 1 gm	00002-7321-25	$ 13.91000		Abbott	Vancomycin 1 mg	00074-6533-01	$ 61.68978
Fujisawa	Pentam 300	00469-0113-10	$ 84.53000		Abbott	Pentamidine	00074-4548-01	$111.40518
Lilly	Oncovin 1 ml	00002-7194-01	$ 29.63900		Pharmacia	Vincasar 1 ml	00013-7456-86	$ 31.73620
Bristol-Myers	Vepesid 5 ml	00015-3095-20	$116.83000		Chiron	Etoposide 5 ml	53905-0291-01	$119.84000
Bristol-Myers	Amikin 2ml	00015-3020-20	$ 29.32870		Abbott	Amikacin 2 ml	00074-1956-01	$ 97.87718
Bristol-Myers	Amikin 2 ml	00015-3020-20	$ 29.32870		Elkins-Sinn	Amikacin 2 ml	00641-0123-23	$ 54.57000
Bristol-Myers	Amikin 2 ml	00015-3020-20	$ 29.32870		Gensia	Amikacin 2 ml	00703-9032-03	$ 55.89680
Pharmacia	Cleocin Phosphate 2 ml	00009-0870-26	$ 6.48420		Abbott	Clindamycin Phosphate 2 ml	00074-4050-01	$ 10.99150
Pharmacia	Cleocin Phosphate 2 ml	00009-0870-26	$ 6.48420		Solopak	Clindamycin Phosphate 2 ml	39769-0226-02	$ 9.15920
Pharmacia	Cleocin Phosphate 4 ml	00009-0775-26	$ 11.86628		Abbott	Clindamycin Phosphate 4 ml	00074-4051-01	$ 20.13340
Pharmacia	Cleocin Phosphate 4 ml	00009-0775-26	$ 11.86628		Solopak	Clindamycin Phosphate 4 ml	39769-0226-04	$ 16.77760

EXAMPLES OF STATES' MEDICAID PROGRAMS PAYING PROVIDERS MORE FOR GENERIC DRUGS THAN THE BRANDS

BRAND				GENERIC					
COMPANY	DRUG	NDC	FLORIDA MEDICAID	COMPANY	DRUG	NDC	RED BOOK "AWP"	"DP"	FLORIDA MEDICAID
Glaxo-Wellcome	Zovirax 500 mg	00173-0995-01	$ 50 47083	Abbott	Acyclovir Sodium 500 mg	00074-4427-01	$95.00	$80.00	$ 84 5500
Glaxo-Wellcome	Zovirax 1 gm	00173-0952-01	$100 94059	Abbott	Acyclovir Sodium 1,000 mg (1 gm)	00074-4452-01	$190.00	$160.00	$169 1000

VEN-A-CARE
OF THE FLORIDA KEYS, INC.
A Home I.V. and Nutritional Service

T-3

KEY WEST, FLA 33
(305) 292-
FAX (305) 292-

June 1, 1998

Honorable Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
Department of Health and Human Services
200 Independence Blvd. S.W.
Hubert Humphrey Building Room 314G
Washington, D. C. 20201

RE: HCFA's PROPOSED METHODOLOGY REVISION FOR PAYMENT OF DRUGS AND BIOLOGICALS.

Dear Ms. DeParle,

We are writing regarding HCFA's proposed regulation for the payment of drugs and biologicals that would revise the method for calculating the median average wholesale price ("AWP") for multiple-source drugs to equal the lower of the median price of the generic AWPs or the lowest brand name AWP. As you may be aware we have for more than six years attempted to assist the Health Care Financing Administration, "HCFA" in limiting certain infusion and inhalation pharmaceutical reimbursements to the reasonable amounts contemplated by United States laws and regulations.

Under HCFA's proposed regulation the Medicare Program will be paying providers for certain drugs at the brand name prices while allowing the provider to purchase and to utilize the much cheaper generic.

This revision may have the undesired effect of somehow legitimatizing what the FBI and the Department of Justice sought to prosecute in 1992 under operation "Goldpill" (see enclosed article *Drug Topics* July 20, 1992). Under Goldpill, the FBI arrested 82 pharmacists and the Department of Justice sought criminal prosecution for crimes including billing the government for brand name drugs while in truth and in fact dispensing cheaper generic.

Your Agency writes that it is taking this action "because of OIG reports and because we believe it is fiscally responsible". We fail to see how any responsible governmental official can possibly construe the act of paying for a brand name drug when cheaper generic are being used as acting "fiscally responsible".

This ill-conceived revision only adds insult to the injury of the fact that Medicare is paying providers more for certain generic drugs than their equivalent brands in the first place.

Sincerely,

Zachary T. Bentley

T. Mark Jones

cc: Mr. Horace Deets, Executive Director, AARP
HHS Secretary, Donna Shalala
HHS Inspector General, June Gibbs Brown
Congressman Fortney "Pete" Stark
Teruni Rosengren, GAO

933 Fleming Street VEN-A-CARE of the Florida Keys, Inc. (305) 292-1635 Key West, Florida 330

AT DEADLINE

Operation Goldpill a bitter pill for R.Ph.s to swallow

For America's most trusted profession, June 30 was a day of shame. On that day—under national press coverage—more than 1,000 FBI agents and 120 other federal law enforcement officers fanned out across the country and began arresting pharmacists and seizing pharmacies.

Based on evidence gathered through undercover operations and electronic surveillance in more than 50 cities, 139 persons were charged with a variety of drug diversion, fraud, and conspiracy charges. Among them were 82 pharmacists and one doctor, the FBI reported.

'Operation Bitterpill': Government officials called Operation Goldpill the biggest criminal fraud investigation in the history of the health-care industry. They vowed that it was far from complete. For pharmacists it might as well have been dubbed Operation Bitterpill, difficult to reconcile with their No. 1 rating of professional trustworthiness in several Gallup Polls. (For pharmacists' reactions, see following story.)

Although final figures from the FBI on the first phase of the probe were not complete at press time, the 56 pharmacies reported closed all seemed to be independently owned. At least in the Chicago area, some cases involved sale of drug samples originally provided to physicians, other health-care professionals, and clinics.

FBI director William S. Sessions said the investigation, which took nearly two years, discovered two major scams. One involved illegally diverting, repackaging, and distributing prescription drugs, generally noncontrolled substances. The second involved intentional excessive or false billing, including dispensing generics and charging Medicaid or private insurers for brand-name drugs. Although the schemes were found in every region—16 FBI field offices took part in the investigations—there did not appear to be a nationwide link.

"I want to assure the American public that at no time during this investigation did the FBI allow tainted or outdated pharmaceuticals to reach the public," Sessions said at a news conference. During "every step of this operation," he said, the FBI worked closely with the Food & Drug Administration to carefully monitor potential sales of inferior medications. "Whenever the FBI or FDA suspected any medications of being adulterated or expired, they were seized. Public safety was paramount, and plans were put in place to ensure that affected customers had continued access to medication."

Federal health officials emphasized that as disturbing as the cases are they should not reflect on all health-care professionals. "The motivation for these illicit schemes was pure greed," said Louis W. Sullivan, M.D., secretary of Health & Human Services. "It is unconscionable for health-care professionals to sacrifice their patients' welfare for economic gain. The medical professionals who would engage in such activities represent only a tiny fraction of the honest, dedicated, and caring men and women in the health professions in America."

FDA commissioner David A. Kessler, M.D., agreed and advised patients with suspicions about their medicines to consult a doctor or pharmacist they trust. "The overwhelming majority of health-care providers have the highest integrity," Kessler said. Patients, he added, should be suspicious of any medicines marked "sample" unless dispensed as a sample from a physician, or if the medicine looks different from those previously purchased. The FDA also operates a hotline that patients and pharmacists can call between 9 A.M. and 9 P.M. EDT. The number is 1 (800)-FDA-5568.

Largest in N.Y. area: The largest diversion operations took place in the New York metropolitan area, where 33 pharmacists were charged and 11 pharmacies and beauty supply stores were seized and closed. FBI officials said a network of people bought Rxs from Medicaid recipients and then, through a complex black-market web, sold them to pharmacies. The scam is well-known (see *Drug Topics*, Nov. 11, 1991) and typically works this way:

A Medicaid recipient, often a drug addict, visits an unscrupulous doctor, describes a nonexistent condition, and gets an Rx for a high-cost brand-name drug. After the prescription is filled, the "patient" sells the drug to a middleman called a "nonman" or a "nonconman" for about 10% of its cost. Later, the middleman sells the drugs to a distributor, who then sells them to another distributor or directly to pharmacies—loose in plastic baggies or garbage bags—at a price well under average wholesale price. Sometimes the drugs are resealed in containers with counterfeit safety seals and bogus manufacturers' packaging.

The second type of fraud involved pharmacies submitting false reimbursement claims to Medicaid or private insurers. Sometimes bills were submitted for brand-names when generics were dispensed; sometimes the drugs were never dispensed. There were cases of multiple bills being submitted for the same Rx. There also were cases of prescription splitting, so the R.Ph. could get two dispensing fees.

Martha McNeill, R.Ph.
Product Manager
Vendor Drug Program
Texas Department of Health
1100 West 49th Street
Austin, TX 78756-3174

SB
SmithKline Beecham
Pharmaceuticals

Dear Ms. McNeill: April 20, 1994

Enclosed please find the completed application for Kytril™ (granisetron hydrochloride) Injection. If there is any further information required, or if you have any questions on the application, please contact me toll free at 1-800-699-3851.

Thank you for your assistance.

Sincerely,

Peg Skelly
SB/CRC-200
8990 Springbrook Drive
Minneapolis, MN 55433

CC: Barry Gershon
Larry Maddock

SB02217

338

C-1

2) PRICE INFORMATION SB02220

Average of suggested wholesale price to pharmacy.	$166.00
Direct price to pharmacy	No direct price
Price to wholesaler and/or distributor	$132.80
Special price to chain warehouse	No special price
Special price to institutional pharmacy (i.e., nursing home, home health care)	No special price
Other price	No other price

3) Please circle the companies to whom you report pricing information.

First Data Bank Price Alert Red Book

Medi-Span Blue Book

4) Do you sell to distributors, repackagers, or relabelers, other than full-service drug wholesalers, who in turn sell your product to the retail trade bearing your NDC number?

No

I certify that the information submitted is correct to the best of my knowledge and that this product is not now in violation of either Federal or State Law. I also agree to inform the Texas Department of Health, in writing, of any changes in formulation, product status, price or availability as herein described, within fifteen (15) days of such change.

Barry Gershon
Responsible Person (Type or Print)

Barry Gershon
Signature

One Franklin Plaza, P.O. Box 7929	Philadelphia	PA	19101
Address	City	State	ZIP

SmithKline Beecham Pharmaceuticals	(215) 751-4000	SB02222
Company Name	Telephone	

Texas Department of Health

David R. Smith, M.D.
Commissioner

1100 West 49th Street
Austin, Texas 78756-3199
(512) 458-7111

Robert A. MacLean, M.D.
Deputy Commissioner

Barry Gershon
SmithKline Beecham Pharm.
One Franklin Plaza/P.O. Box 7929
Philadelphia, PA 19101

May 16, 1994.

U-2

Dear Mr. Gershon:

This will advise you that your application for inclusion of the drug Kytril on the list of drug products for which the Texas Vendor Drug Program will reimburse pharmacies on Medicaid prescriptions has been approved. All claims should be submitted under product NDC number. The effective date for this approval is April 28, 1994.

Thank you for your submission of these products. Your cooperation in keeping me informed of any changes to your product line, including changes in cost to wholesalers and retail/chain pharmacies, is hereby requested and required.

Sincerely,

Martha McNeill, R.Ph.

Martha McNeill, R.Ph.
Product Manager
Vendor Drug Program

SB00740

RECEIVED
MAY 2 3 1994
B. GERSHON

FLORIDA INFUSION CHEMONET

AUGUST 1994

KLING GAUZE STERILE 4 X 5Y 12/BAG 6924	12.12
KYTRIL INJECTION 1MG/ML 1ML VIAL	118.90 *
LABEL, MEDICATION ADDED 500/ROLL	9.84

*** FREE PRIORITY NEXT DAY AIR DELIVERY**

V-3

1-800-624-0152

FLORIDA INFUSION CHEMONET

OCTOBER 1994

ZOFRAN®

2mg/mL 20mL

172^{92}*

169^{45}*

For Case of 40 Vials

KYTRIL®

1mg/mL 1mL

LOWEST PRICE EVER IN THE PHYSICIAN MARKET

112^{75}

For 30 Vials or more

*FOR PHYSICIANS AND CLINICS ONLY

VALID FROM OCTOBER 10 - OCTOBER 31, 1994

KYTRIL™

We have been notified that, effective April 1, 1995, SmithKline's long running promotional rebate for Kytril purchases will come to a very successful conclusion. In anticipation of the impact the loss of this rebate is certain to have, and to encourage you to stock up, we are offering our lowest price ever on Kytril. Order **12** vials or more and take advantage of the sale price of **$111.95**! This offer is valid through February 28, 1995. Once rebates are removed, our best estimate is that prices will rise to **$118** and beyond. Please plan now.

$111.95

12 vials or more

Valid until February 28, 1995

FLORIDA INFUSION

Please fill out the following information for consideration on Texas Medicaid

INCLUDE A COPY OF FILE CARD, PACKAGE INSERT AND OR MATERIAL FOR PHYSICIANS

1. DRUG DESCRIPTION

NDC NO: 0088-1206-32 ✓ (multiple package size of same be included)		PACKAGE QTY: 5mL/100mg vial, 1-ct. ✓ strength products may
PRODUCT BRAND NAME: Anzemet ✓		
GENERIC NAME: dolasetron mesylate		
PRIVATE BRAND NAME: not applicable (if applicable)		
DRUG STRENGTH: 100mg/ 5mL ✓		
COLOR: None ✓	FLAVOR: None ✓	*ORANGE BOOK RATING: NOT RATED
DOSAGE FORM: injectable ✓	IS THIS DRUG LEGEND OR OTC? LEGEND ✓	DEA SCHEDULE OF THE DRUG: No

U-4

25.47960

PRICE INFORMATION

AVERAGE OF SUGGESTED WHOLESALE PRICE TO PHARMACY	$ 149.88 ✓
DIRECT PRICE TO PHARMACY	$ None
PRICE TO WHOLESALER AND/OR DISTRIBUTOR	$ 124.90
SPECIAL PRICE TO CHAIN WAREHOUSE	$ None
SPECIAL PRICE TO INSTITUTIONAL PHARMACY, i.e., (Nursing Home, Home Health Care	$ None
OTHER PRICE	$ None

Attach copies of price lists - one set of price lists is sufficient for multiple submittals.

3. Please circle the companies to whom you report pricing information.

FIRST DATA BANK PRICE ALERT RED BOOK

MEDI-SPAN BLUE BOOK

OTHERS: _____

Do you sell to distributors, repackagers, or relabelers, other than full-service drug wholesalers, who in turn sell your product to the retail trade bearing your NDC number? None

If yes, attach a listing.

I certify that the information submitted is correct to the best of my knowledge and that this product is not now in violation of either Federal or State Law. I also agree to inform the Texas Department of Health, in writing, of any changes in formulation, product status, price or availability as herein described, within fifteen (15) days of such change.

Susan D. Zalenski
Responsible Person (Type or Print)

Susan D. Zalenski
Signature

Director, State Government Relations
Title

10236 Marion Park Drive, P. O. Box 9627 Kansas City, MO 64137
Address City State Zip

Hoechst Marion Roussel, Inc. (816) 966-3137
Company Name Telephone

Now Available!

Anzemet™

A New 5-HT$_3$ Receptor Antagonist

(dolasetron mesylate injection/tablets)
from Hoechst Marion Roussel

ONCOLOGY THERAPEUTICS NETWORK

Excellent Efficacy and Safety Profile

Great Value!

CATALOG NUMBER	NDC	BRAND NAME	ITEM	UNIT SIZE	ORDER QUANTITY	PRICE/ UNIT	AWP
900-250	0088-1206-32	Anzemet	dolasetron mesylate	100 mg vial	1	$70.00	$149.88
970-300	0088-1203-05	Anzemet	dolasetron mesylate	100 mg tablets	5	$289.75	$330.00
970-305	0088-1203-29	Anzemet	dolasetron mesylate	100 mg tablets blister pack	5	$289.75	$330.00
970-310	0088-1203-43	Anzemet	dolasetron mesylate	100 mg tablets unit dose	10	$579.50	$660.00

U-5

Outstanding Support:

Reimbursement and Patient Assistance Program Hotline 1-888-895-2219

Call the Anzemet Hotline for help with reimbursement and patient assistance programs, Monday through Friday between 10:00 am and 6:00 pm ET.

Call OTN today at 1-800-482-6700 to place your order!

V

TOPIC: QUESTION ADDRESSING THE CONSERVATIVE NATURE OF THE GAO ESTIMATES OF PROFITS FROM THESE DRUGS.

Mr. Bentley, the spreads or profits noted in the IG and GAO testimony are quite significant. I understand that these profits are based on prices that are available to Ven-a-Care, which is a very small home infusion pharmacy. Is that correct? For larger concerns, such as U.S. Oncology, I assume those buyers could get even better prices, resulting in more profits for the provider and a larger expense for Medicare and the beneficiary.

How many providers in the health care industry can buy many of these drugs at the price US Oncology is able to negotiate and how many at the price Venacare is able to negotiate. In your opinion, how conservative are the IG and GAO estimates for the overcharging to the Medicare sytem?

Vol 2. 1

ONE HUNDRED SEVENTH CONGRESS

U.S. House of Representatives

Committee on Energy and Commerce

Washington, DC 20515–6115

W.J. "BILLY" TAUZIN, LOUISIANA,
CHAIRMAN

September 5, 2001

Mr. Charles Rice
Chief Executive Office
Dey Laboratories
2751 Napa Valley Corporate Drive
Napa, CA 94558

Dear Mr. Rice:

As you know, the House Energy and Commerce Committee has been conducting an exhaustive investigation into the issue of the pricing of Medicare-covered drugs over the past several years. In furtherance of its principal goal of protecting the Medicare program and its beneficiaries from unnecessarily inflated costs for Medicare-covered drugs, the Committee intends to hold a hearing on September 12, 2001, before its Subcommittees on Health and Oversight and Investigations, to further explore how the abuses in the current system can be eliminated.

We understand that Committee staff recently extended an invitation for you to testify at this hearing. We further understand that this invitation was declined, based upon concerns relating to the ongoing investigation being conducted by the Texas Attorney General's office. While we fully appreciate these concerns, we would urge you to reconsider this decision. It is imperative for the Subcommittees to hear from drug manufacturers about their pricing practices under the current Medicare reimbursement system, which result in significant "spreads" between the reimbursement price and the actual price paid by providers for these drugs. This type of abuse is costing the taxpayers, the Medicare system, and Medicare beneficiaries hundreds of millions of dollars every year, and must be stopped.

We sincerely hope that you will reconsider this request, and agree to testify at the hearing on September 12th. Please respond in writing to this request no later than close of business on Friday, September 7, 2001, and if you should choose to decline to testify, please provide your reasons for doing so. If you should have any questions regarding this matter, please contact Charles Clapton, Committee counsel, at (202) 226-2424.

Sincerely,

Michael Bilirakis
Chairman
Subcommittee on Health

James Greenwood
Chairman
Subcommittee on Oversight
& Investigations

cc: The Honorable W.J. "Billy" Tauzin, Chairman
The Honorable John Dingell, Ranking Member
The Honorable Sherrod Brown, Ranking Member, Subcommittee on Health
The Honorable Peter Deutsch, Ranking Member, Subcommittee on Oversight & Investigations

ONE HUNDRED SEVENTH CONGRESS
U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

W.J. "BILLY" TAUZIN, LOUISIANA,
CHAIRMAN

September 5, 2001

Wolfgang Plischke
President, North America
Bayer Corporation, Pharmaceuticals Division
400 Morgan Lane
West Haven, CT 06516

Dear Mr. Plischke:

As you know, the House Energy and Commerce Committee has been conducting an exhaustive investigation into the issue of the pricing of Medicare-covered drugs over the past several years. In furtherance of its principal goal of protecting the Medicare program and its beneficiaries from unnecessarily inflated costs for Medicare-covered drugs, the Committee intends to hold a hearing on September 12, 2001, before its Subcommittees on Health and Oversight and Investigations, to further explore how the abuses in the current system can be eliminated.

We understand that Committee staff recently extended an invitation for you to testify at this hearing. We further understand that this invitation was declined, based upon concerns relating to the recent recall of Baycol and the demands that this has placed upon your staff. While we fully appreciate these concerns, we would urge you to reconsider this decision. It is imperative for the Subcommittees to hear from drug manufacturers about their pricing practices under the current Medicare reimbursement system, which result in significant "spreads" between the reimbursement price and the actual price paid by providers for these drugs. This type of abuse is costing both the taxpayers, the Medicare system and Medicare beneficiaries hundreds of millions of dollars every year, and must be stopped.

We sincerely hope that you will reconsider this request, and agree to testify at the hearing on September 12th. Please respond in writing to this request no later than close of business on Friday, September 7, 2001, and if you should choose to decline to testify, please provide you reasons for doing so. If you should have any questions regarding this matter, please contact Charles Clapton, Committee counsel, at (202) 226-2424.

Sincerely,

Michael Bilirakis
Chairman
Subcommittee on Health

James Greenwood
Chairman
Subcommittee on Oversight
& Investigations

cc: The Honorable W.J. "Billy" Tauzin, Chairman
The Honorable John Dingell, Ranking Member
The Honorable Sherrod Brown, Ranking Member, Subcommittee on Health
The Honorable Peter Deutsch, Ranking Member, Subcommittee on Oversight & Investigations

ONE HUNDRED SEVENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

W.J. "BILLY" TAUZIN, LOUISIANA,
CHAIRMAN

September 5, 2001

Miles White
Chairman and CEO
Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064

Dear Mr. White:

As you know, the House Energy and Commerce Committee has been conducting an exhaustive investigation into the issue of the pricing of Medicare-covered drugs over the past several years. In furtherance of its principal goal of protecting the Medicare program and its beneficiaries from unnecessarily inflated costs for Medicare-covered drugs, the Committee intends to hold a hearing on September 12, 2001, before its Subcommittees on Health and Oversight and Investigations, to further explore how the abuses in the current system can be eliminated.

We understand that Committee staff recently extended an invitation for you to testify at this hearing. We further understand that this invitation was declined. Given the important role that drug manufacturers play in the current reimbursement system for Medicare-covered drugs, we would urge you to reconsider this decision. It is imperative for the Subcommittees to hear from drug manufacturers about their pricing practices under the current Medicare reimbursement system, which result in significant "spreads" between the reimbursement price and the actual price paid by providers for these drugs. This type of abuse is costing the taxpayers, the Medicare system, and Medicare beneficiaries hundreds of millions of dollars every year, and must be stopped.

We sincerely hope that you will reconsider this request, and agree to testify at the hearing on September 12th. Please respond in writing to this request no later than close of business on Friday, September 7, 2001, and if you should choose to decline to testify, please provide you reasons for doing so. If you should have any questions regarding this matter, please contact Charles Clapton, Committee counsel, at (202) 226-2424.

Sincerely,

Michael Bilirakis
Chairman
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Chairman
Subcommittee on Oversight
& Investigations

cc: The Honorable W.J. "Billy" Tauzin, Chairman
The Honorable John Dingell, Ranking Member
The Honorable Sherrod Brown, Ranking Member, Subcommittee on Health
The Honorable Peter Deutsch, Ranking Member, Subcommittee on Oversight & Investigations

ABBOTT

Mark E. Dalmak
Vice President, Government Affairs

Abbott Laboratories
Dept. 0690 - R1D
100 Abbott Park Road
Abbott Park, IL 60064-6021

Telephone 847 937 6213
Facsimile 847 937 9555

September 7, 2001

VIA FACSIMILE--(202) 226-2447

The Honorable Michael Bilirakis and The Honorable James Greenwood
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairmen Bilirakis and Greenwood.

Since Mr. White is out of the country, he has requested that I respond to your letter dated September 5, 2001. After careful review of this matter, we have reconsidered our position declining your invitation to appear at the September 12 hearing.

As you may be aware, at the request of Congressman Greenwood, I visited with him and members of the Subcommittee staff to discuss this issue. While we commend the Committee for its efforts, we do not believe that we would be able to provide any real insights that would be of value to the Committee. For this reason we respectfully decline your invitation to testify at the hearing.

Sincerely,

Mark E. Dalmak

MEB:jm

Bayer

Pharmaceutical
Division

Mark A. Ryan
Vice President
Public Policy & Communications

The Honorable James C. Greenwood, M.C.
United States House of Representatives
Chairman, Subcommittee on Oversight and Investigations
2436 Rayburn House Office Building
Washington, DC 20515

September 7, 2001

Dear Chairman Greenwood:

I have just recently received your invitation to Dr. Plischke, President of Bayer Pharmaceutical North America, to appear before the House of Representatives Subcommittee on Health and the Subcommittee on Oversight and Investigations hearing on "Medicare Drug Reimbursement" scheduled for September 12, 2001. This is a subject that we at Bayer have spent many hours examining and consider to be of great importance to the patients using our products, as well as to third-party payers, such as the federal government.

To meet a special request of the Oversight and Investigations Subcommittee, Dr. Plischke re-routed his trip from Japan to make a personal visit with you concerning these issues on June 6th, 2001. As you may know, Bayer has entered into an agreement with the Department of Justice and is currently adhering to a "Corporate Compliance Program" relating to just this issue. This information is public knowledge and discloses the way in which we price our products.

Since then Bayer Pharmaceutical has voluntarily withdrawn Baycol ®, our cholesterol-lowering agent. This withdrawal of one of our company's leading products has required all the resources of our company, and will for the near future. Dr. Plischke is currently not in the United States and is also unavailable for the September 12th hearing. I have asked our legal counsel in Washington DC, Paul Kalb of Sidley Austin Brown & Wood, to furnish your committee with our Corporate Compliance Program and information relating to the Department of Justice and State agreements.

On behalf of Bayer Pharmaceutical and Dr. Plischke, I hope this will further your committee examination of this important issue. Please know that we all commend your untiring efforts to improve the health and well-being of our citizens.

Sincerely,

Mark A. Ryan

Bayer Corporation
400 Morgan Lane
West Haven, CT 06516-4175
Phone 203 812-8439
Fax 203 812-3017
mark.a.ryan.b@bayer.com

Sep-10-01 09:18am From-Coudert Brothers T-481 P.001/002 F-514

DEY, L.P.
2751 Napa Valley Corporate Drive
Napa CA 94558
TEL (707) 224-3200 FAX (707) 224-3335

September 10, 2001

The Honorable Michael Bilirakis
The Honorable James Greenwood
Committee on Commerce
Subcommittee on Health
Subcommittee on Investigations and Oversight
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairmen Bilirakis and Greenwood:

After careful consideration and much deliberation, I must respectfully decline your invitation to appear before the joint Energy and Commerce Subcommittees on Investigations and Oversight, and Health at this time. Appearing as the only pharmaceutical manufacturer puts me in a position to appear to be speaking on behalf of the entire pharmaceutical industry, something I would never presume to do.

As I have indicated, should you assemble a panel of pharmaceutical manufacturers to discuss the reimbursement issue in the future, I will participate.

I continue to offer my knowledge and time to the efforts of the Committee to draft legislative improvements to current pharmaceutical reimbursement policies. To that end, I offer you and the Committee my thoughts, which I hope will help you in your deliberations.

In my judgment, any legislative improvements must consider the following:

1. **Critical terms need to be defined by statute so all participants can be assured that they are fully complying with the law.**

2. **Reimbursement policy must adequately consider the costs imposed on each participant in the value chain for prescription drugs.**

3. **There should be a level playing field that encourages and promotes competition.**

To the first point, Average Wholesale Price (AWP) has never been defined by statute. Dating back more than 20 years, there are public reports, investigations, studies, court and administrative rulings, recommendations from HHS, and Presidential pronouncements, confirming that AWP is not a "true" price. While the industry, regulators and public officials have understood this, some are now asserting that a different meaning exists. Without terms defined in statute, controversy will persist.

Second, adequate patient care involves numerous stakeholders including researchers, manufacturers, distributors, dispensers, prescribers and service providers. In total, all of these constitute the value chain for prescription drugs, each legitimately seeking appropriate compensation for its services. If prescription drugs were reimbursed merely at or slightly above acquisition cost, that would disregard the value contributed by non-manufacturers to the care of patients. This could result in inadequate provision of care and ultimately higher costs to the government and the patient.

Third, piecemeal changes can steer decisions in the wrong direction. Some attempted solutions, while well intended, can be more costly than anything found in the current system. As an example, the proposed "quick fix" last year to change the reimbursement for 50 pharmaceutical products, which Congress rightly suspended, is an example of an action that disregards the importance of competition as well as the value chain. This type of selective restriction forces the market to higher priced products, which would have immediately created an un-level playing field and increased costs to the government.

In closing I believe there would be much to gain by getting all the stakeholders together with officials at HHS to discuss and propose solutions. To our knowledge, no such effort has been undertaken to date. I also think it would be helpful to hear from non-government payers on their methods of handling reimbursement issues.

I commend your efforts at tackling these issues and remain committed to assist you and the Committee.

Sincerely,

Charles A. Rice
President & CEO

Bayer

Pharmaceutical
Division

Mark A. Ryan
Vice President
Public Policy & Communications

The Honorable Michael Bilirakis, M.C.
United States House of Representatives
Chairman, Subcommittee on Health
2289 Rayburn House Office Building
Washington, DC 20515

September 7, 2001

Dear Chairman Bilirakis:

I have just recently received your invitation to Dr. Plischke, President of Bayer Pharmaceutical North America, to appear before the House of Representatives Subcommittee on Health and the Subcommittee on Oversight and Investigations hearing on "Medicare Drug Reimbursement" scheduled for September 12, 2001. This is a subject that we at Bayer have spent many hours examining and consider to be of great importance to the patients using our products, as well as to third-party payers, such as the federal government.

To meet a special request of the Oversight and Investigations Subcommittee, Dr. Plischke re-routed his trip from Japan to make a personal visit with Chairman Greenwood concerning these issues on June 6, 2001. As you may know, Bayer has entered into an agreement with the Department of Justice and is currently adhering to a "Corporate Compliance Program" relating to just this issue. This information is public knowledge and discloses the way in which we price our products.

As widely reported in the press, Bayer Pharmaceutical has very recently voluntarily withdrawn Baycol ®, our cholesterol-lowering agent. This withdrawal of one of our company's leading products has required all the resources of our company, and will for the near future. Dr. Plischke is currently not in the United States and is also unavailable would for the September 12th hearing. I have asked our legal counsel in Washington DC, Paul Kalb of Sidley Austin Brown & Wood, to furnish your committee with our Corporate Compliance Program and information relating to the Department of Justice and State agreements.

On behalf of Bayer Pharmaceutical and Dr. Plischke, I hope this will further your committee examination of this important issue. Please know that we all commend your untiring efforts to improve the health and well-being of our citizens.

Sincerely,

Mark A. Ryan

Bayer Corporation
400 Morgan Lane
West Haven, CT 06516-4175
Phone 203 812-5439
Fax 203 812-3017
mark-a.ryan.b@bayer.com

Vol. 2.
2

Medicare Payments for Prescription Drugs

Response to Request from
Representative W. J. Tauzin

June 2001

OEI-03-01-00490

U.S. Department of Health and Human Services
Office of Inspector General
Office of Evaluation and Inspections

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUN 20 2001

The Honorable W. J. Tauzin
Chairman, Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Tauzin:

In response to your request, we are providing you with information on the amount of beneficiary coinsurance that would be saved if Medicare drug payments were based on prices available to other sources. In this report, we compared Medicare prices for 24 drugs to Department of Veterans Affairs prices and to wholesale catalog prices. We have enclosed four tables which illustrate the impact excessive payment amounts have on the Medicare program and its beneficiaries.

This report provides data clearly demonstrating that Medicare pays too much for prescription drugs. For example, we found that Medicare would save $1.9 billion a year if 24 drugs were reimbursed at prices available to the Department of Veterans Affairs. Over $380 million of this savings would directly impact Medicare beneficiaries in the form of reduced coinsurance payments. In some cases, the Department of Veterans Affairs price for a drug was less than the amount a Medicare beneficiary would pay in coinsurance. More conservatively, Medicare and its beneficiaries would save $887 million a year by paying the actual wholesale prices available to physicians and suppliers for these 24 drugs. Beneficiaries would pay over $175 million less in coinsurance if Medicare paid for these drugs based on catalog prices.

The majority of the data in this report was first presented in our September 2000 report, "Medicare Reimbursement of Prescription Drugs," (OEI-03-00-00310). The pricing data was collected in the second quarter of 2000 from Medicare carriers, the Department of Veterans Affairs, and several wholesale pricing catalogs. In order to provide a current estimate of potential savings, we have updated the total Medicare allowed charges data from the figures which appeared in the original report.

If you have any questions about this report, or if we can provide further assistance, please call me or George Grob, Deputy Inspector General for Evaluation and Inspections, or have your staff contact Robert Vito at (215) 861-4558.

Sincerely,

Helen Albert
Director, External Affairs

Enclosures

TABLE OF CONTENTS

TABLE 1:

MEDICARE AND THE DEPARTMENT OF VETERANS AFFAIRS UNIT COSTS AND BENEFICIARY COINSURANCE

HCPCS CODE	GENERIC DRUG NAME	2000 MEDIAN PRICES		VA PRICE AS PERCENTAGE OF MEDICARE PRICE	20% MEDICARE COINSURANCE	
		MEDICARE	VA		CURRENT	BASED ON VA PRICE
J0640	Leucovorin Calcium, 50 mg	$18.02	$1.63	9.0%	$3.60	$0.33
J1260	Dolasetron Mesylate, 10 mg	$14.82	$4.95	33.4%	$2.96	$0.99
J1440	Filgrastim, 300 mcg	$171.38	$130.72	76.3%	$34.28	$26.14
J1441	Filgrastim, 480 mcg	$273.03	$208.23	76.3%	$54.61	$41.65
J1562	Immune Globulin, 5g	$396.63	$110.54	27.9%	$79.33	$22.11
J1626	Granisetron HCl, 100 mcg	$18.54	$7.81	42.1%	$3.71	$1.56
J2405	Ondansetron HCl, 1 mg	$6.09	$3.94	64.7%	$1.22	$0.79
J2430	Pamidronate Disodium, 30	$243.56	$203.45	83.5%	$48.71	$40.69
J2820	Sargramostim, 50 mcg	$27.41	$10.06	36.7%	$5.48	$2.01
J7608	Acetylcysteine, per g	$5.05	$1.50	29.7%	$1.01	$0.30
J7619	Albuterol Sulfate, per mg	$0.47	$0.07	14.9%	$0.09	$0.01
J7644	Ipratropium Bromide, per mg	$3.34	$0.84	25.2%	$0.67	$0.17
J9000	Doxorubicin HCl, 10 mg	$42.92	$6.29	14.7%	$8.58	$1.26
J9045	Carboplatin, 50 mg	$101.37	$41.14	40.6%	$20.27	$8.23
J9170	Docetaxel, 20 mg	$283.65	$151.77	53.5%	$56.73	$30.35
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.86	84.6%	$17.69	$14.97
J9202	Goserelin Acetate, 3.6 mg	$446.49	$214.87	48.1%	$89.30	$42.97
J9206	Irinotecan, 20 mg	$117.81	$75.45	64.0%	$23.56	$15.09
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$257.00	43.4%	$118.52	$51.40
J9265	Paclitaxel, 30 mg	$173.49	$107.59	62.0%	$34.70	$21.52
J9310	Rituximab, 100 mg	$420.29	$239.58	57.0%	$84.06	$47.92
J9350	Topotecan, 4 mg	$573.75	$307.25	53.6%	$114.75	$61.45
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$46.20	61.2%	$15.10	$9.24
Q0136	Epoetin Alfa, per 1000 units	$11.40	$7.22	63.3%	$2.28	$1.44

TABLE 2:

MEDICARE AND THE DEPARTMENT OF VETERANS AFFAIRS
POTENTIAL MEDICARE AND BENEFICIARY SAVINGS

HCPCS CODE	GENERIC DRUG NAME	2000 MEDIAN PRICES		PERCENT SAVINGS	2000 ALLOWED CHARGES	POTENTIAL SAVINGS		
		MEDICARE	VA			MEDICARE	BENEFICIARY	TOTAL
J0640	Leucovorin Calcium, 50 mg	$18.02	$1.63	91.0%	$69,228,203	$50,372,930	$12,593,232	$62,966,162
J1260	Dolasetron Mesylate, 10 mg	$14.82	$4.95	66.6%	$82,482,309	$43,946,040	$10,986,510	$54,932,550
J1440	Filgrastim, 300 mcg	$171.38	$130.72	23.7%	$51,133,657	$9,705,191	$2,426,298	$12,131,488
J1441	Filgrastim, 480 mcg	$273.03	$208.23	23.7%	$83,837,285	$15,918,122	$3,979,531	$19,897,653
J1562	Immune Globulin, 5g	$396.63	$110.54	72.1%	$49,903,101	$28,796,164	$7,199,041	$35,995,205
J1626	Granisetron HCl, 100 mcg	$18.54	$7.81	57.9%	$42,674,561	$19,758,276	$4,939,569	$24,697,845
J2405	Ondansetron HCl, 1 mg	$6.09	$3.94	35.3%	$55,003,100	$15,534,537	$3,883,634	$19,418,172
J2430	Pamidronate Disodium, 30 mg	$243.56	$203.45	16.5%	$156,095,768	$20,564,957	$5,141,239	$25,706,197
J2820	Sargramostim, 50 mcg	$27.41	$10.06	63.3%	$27,758,142	$14,056,294	$3,514,073	$17,570,367
J7608	Acetylcysteine, per g	$5.05	$1.50	70.3%	$22,452,105	$12,626,530	$3,156,633	$15,783,163
J7619	Albuterol Sulfate, per mg	$0.47	$0.07	85.1%	$261,270,168	$177,886,072	$44,471,518	$222,357,590
J7644	Ipratropium Bromide, per mg	$3.34	$0.84	74.9%	$310,310,047	$185,814,399	$46,453,600	$232,267,999
J9000	Doxorubicin HCl, 10 mg	$42.92	$6.29	85.3%	$30,586,166	$20,882,969	$5,220,742	$26,103,711
J9045	Carboplatin, 50 mg	$101.37	$41.14	59.4%	$140,046,625	$66,568,083	$16,642,021	$83,210,104
J9170	Docetaxel, 20 mg	$283.65	$151.77	46.5%	$110,792,891	$41,209,565	$10,302,391	$51,511,957
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.86	15.4%	$100,322,242	$12,338,978	$3,084,744	$15,423,722
J9202	Goserelin Acetate, 3.6 mg	$446.49	$214.87	51.9%	$375,955,270	$156,023,668	$39,005,917	$195,029,586
J9206	Irinotecan, 20 mg	$117.81	$75.45	36.0%	$117,789,971	$33,882,239	$8,470,560	$42,352,798
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$257.00	56.6%	$633,720,145	$287,109,660	$71,777,415	$358,887,075
J9265	Paclitaxel, 30 mg	$173.49	$107.59	38.0%	$284,530,532	$86,462,906	$21,615,727	$108,078,633
J9310	Rituximab, 100 mg	$420.29	$239.58	43.0%	$135,054,269	$46,454,890	$11,613,722	$58,068,612
J9350	Topotecan, 4 mg	$573.75	$307.25	46.4%	$34,885,298	$12,963,042	$3,240,761	$16,203,803
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$46.20	38.8%	$27,866,679	$8,651,589	$2,162,897	$10,814,486
Q0136	Epoetin Alfa, per 1000 units	$11.40	$7.22	36.7%	$536,916,452	$157,495,493	$39,373,873	$196,869,366
TOTAL FOR 24 DRUGS					**$3,740,614,986**	**$1,525,022,594**	**$381,255,648**	**$1,906,278,242**

TABLE 3:

MEDICARE AND WHOLESALE CATALOGS
UNIT COSTS AND BENEFICIARY COINSURANCE

HCPCS CODE	GENERIC DRUG NAME	2000 MEDIAN PRICES		CATALOG PRICE AS PERCENTAGE OF MEDICARE PRICE	20% MEDICARE COINSURANCE	
		MEDICARE	CATALOGS		CURRENT	BASED ON CATALOG PRICE
J0640	Leucovorin Calcium, 50 mg	$18.02	$2.94	16.3%	$3.60	$0.59
J1260	Dolasetron Mesylate, 10 mg	$14.82	$8.29	55.9%	$2.96	$1.66
J1440	Filgrastim, 300 mcg	$171.38	$144.30	84.2%	$34.28	$28.86
J1441	Filgrastim, 480 mcg	$273.03	$229.90	84.2%	$54.61	$45.98
J1562	Immune Globulin, 5g	$396.63	$300.00	75.6%	$79.33	$60.00
J1626	Granisetron HCl, 100 mcg	$18.54	$13.81	74.5%	$3.71	$2.76
J2405	Ondansetron HCl, 1 mg	$6.09	$5.49	90.1%	$1.22	$1.10
J2430	Pamidronate Disodium, 30	$243.56	$223.26	91.7%	$48.71	$44.65
J2820	Sargramostim, 50 mcg	$27.41	$23.13	84.4%	$5.48	$4.63
J7608	Acetylcysteine, per g	$5.05	$3.38	66.9%	$1.01	$0.68
J7619	Albuterol Sulfate, per mg	$0.47	$0.13	27.7%	$0.09	$0.03
J7644	Ipratropium Bromide, per mg	$3.34	$1.53	45.8%	$0.67	$0.31
J9000	Doxorubicin HCl, 10 mg	$42.92	$10.08	23.5%	$8.58	$2.02
J9045	Carboplatin, 50 mg	$101.37	$87.79	86.6%	$20.27	$17.56
J9170	Docetaxel, 20 mg	$283.65	$238.86	84.2%	$56.73	$47.77
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.49	84.2%	$17.69	$14.90
J9202	Goserelin Acetate, 3.6 mg	$446.49	$375.99	84.2%	$89.30	$75.20
J9206	Irinotecan, 20 mg	$117.81	$98.63	83.7%	$23.56	$19.73
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$499.03	84.2%	$118.52	$99.81
J9265	Paclitaxel, 30 mg	$173.49	$146.10	84.2%	$34.70	$29.22
J9310	Rituximab, 100 mg	$420.29	$353.93	84.2%	$84.06	$70.79
J9350	Topotecan, 4 mg	$573.75	$507.32	88.4%	$114.75	$101.46
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$64.11	84.9%	$15.10	$12.82
Q0136	Epoetin Alfa, per 1000 units	$11.40	$10.72	94.0%	$2.28	$2.14

TABLE 4:

MEDICARE AND WHOLESALE CATALOGS:
POTENTIAL MEDICARE AND BENEFICIARY SAVINGS

HCPCS CODE	GENERIC DRUG NAME	2000 MEDIAN PRICES		PERCENT SAVINGS	2000 ALLOWED CHARGES	POTENTIAL SAVINGS		
		MEDICARE	CATALOGS			MEDICARE	BENEFICIARY	TOTAL
J0640	Leucovorin Calcium, 50 mg	$18.02	$2.94	83.7%	$69,228,203	$46,346,784	$11,586,696	$57,933,480
J1260	Dolasetron Mesylate, 10 mg	$14.82	$8.29	44.1%	$82,482,309	$29,074,736	$7,268,684	$36,343,420
J1440	Filgrastim, 300 mcg	$171.38	$144.30	15.8%	$51,133,657	$6,463,762	$1,615,941	$8,079,703
J1441	Filgrastim, 480 mcg	$273.03	$229.90	15.8%	$83,837,285	$10,594,886	$2,648,721	$13,243,607
J1562	Immune Globulin, 5g	$396.63	$300.00	24.4%	$49,903,101	$9,726,217	$2,431,554	$12,157,771
J1626	Granisetron HCl, 100 mcg	$18.54	$13.81	25.5%	$42,674,561	$8,709,846	$2,177,461	$10,887,307
J2405	Ondansetron HCl, 1 mg	$6.09	$5.49	9.9%	$55,003,100	$4,335,220	$1,083,805	$5,419,025
J2430	Pamidronate Disodium, 30 mg	$243.56	$223.26	8.3%	$156,095,768	$10,408,094	$2,602,023	$13,010,117
J2820	Sargramostim, 50 mcg	$27.41	$23.13	15.6%	$27,758,142	$3,467,489	$866,872	$4,334,361
J7608	Acetylcysteine, per g	$5.05	$3.38	33.1%	$22,452,105	$5,939,804	$1,484,951	$7,424,756
J7619	Albuterol Sulfate, per mg	$0.47	$0.13	72.3%	$261,270,168	$151,203,161	$37,800,790	$189,003,951
J7644	Ipratropium Bromide, per mg	$3.34	$1.53	54.2%	$310,310,047	$134,529,625	$33,632,406	$168,162,031
J9000	Doxorubicin HCl, 10 mg	$42.92	$10.08	76.5%	$30,586,166	$18,722,268	$4,680,567	$23,402,835
J9045	Carboplatin, 50 mg	$101.37	$87.79	13.4%	$140,046,625	$15,009,041	$3,752,260	$18,761,302
J9170	Docetaxel, 20 mg	$283.65	$238.86	15.8%	$110,792,891	$13,995,878	$3,498,970	$17,494,848
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.49	15.8%	$100,322,242	$12,674,671	$3,168,668	$15,843,338
J9202	Goserelin Acetate, 3.6 mg	$446.49	$375.99	15.8%	$375,955,270	$47,490,150	$11,872,538	$59,362,688
J9206	Irinotecan, 20 mg	$117.81	$98.63	16.3%	$117,789,971	$15,341,391	$3,835,348	$19,176,739
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$499.03	15.8%	$633,720,145	$80,050,211	$20,012,553	$100,062,764
J9265	Paclitaxel, 30 mg	$173.49	$146.10	15.8%	$284,530,532	$35,936,556	$8,984,139	$44,920,694
J9310	Rituximab, 100 mg	$420.29	$353.93	15.8%	$135,054,269	$17,059,081	$4,264,770	$21,323,851
J9350	Topotecan, 4 mg	$573.75	$507.32	11.6%	$34,885,298	$3,231,275	$807,819	$4,039,094
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$64.11	15.1%	$27,866,679	$3,363,194	$840,799	$4,203,993
Q0136	Epoetin Alfa, per 1000 units	$11.40	$10.72	6.0%	$536,916,452	$25,621,276	$6,405,319	$32,026,595
TOTAL FOR 24 DRUGS					**$3,740,614,986**	**$709,294,617**	**$177,323,654**	**$886,618,271**

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Congressional Research Service

Memorandum August 31, 2001

TO: House Committee on Energy and Commerce
Attention: Charles M. Clapton

FROM: Thomas J. Nicola
Legislative Attorney
American Law Division

SUBJECT: Regulatory and Legislative History of Medicare Drug Reimbursement Based on Average Wholesale Price

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This memorandum responds to a request for a regulatory and legislative history of Medicare drug reimbursement based on the average wholesale price (AWP) of the drug. An AWP is fixed by publishers based on information submitted by drug manufacturers, suppliers, and distributors. The AWP is printed in the wholesale price guides, *Drug Topics Red Book*, *Price Alert*, and *Medispan*.

Although Medicare generally does not pay for prescription drugs under Part B, Supplemental Insurance Benefits for the Aged and Disabled, it does pay for drugs and biologicals that cannot be self-administered, as determined by regulations, and furnished as an incident to a physician's professional service and commonly either rendered without charge or included in the physician's bill. Section 1861(s)(2) of the Social Security Act, 42 U.S.C. 1395x(s)(2). These are sometimes referred to as "incident to" drugs and biologicals and consist of those that are furnished by injection or infusion, including chemotherapy agents. (Generally, this discussion will use the term "drugs" to encompass both "drugs and biologicals.") Until 1992, some carriers reportedly based payment for these agents on the physician's estimated cost of the drug using a wholesale price guide such as the *Red Book*, while other carriers based payment on actual acquisition costs determined on the basis of carrier surveys[1]. 58 *Fed. Reg.* 25800 (June 5, 1991).

Since the beginning of the Medicare program in 1965, Medicare policy had been to base payment on incident to drugs on the estimated acquisition costs, what was called the "reasonable charge" system. *Id.* In June of 1991, in a notice of proposed rulemaking of a

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[1] Prior to 1992, carriers' use of the *Red Book* and other wholesale price guides as sources of average wholesale prices appears to have been based on the Medicare Carriers Manual, part 3, section 5202, which referred to them. Use of carrier surveys appears to have been impeded by the Office of Management and Budget in response to a Paperwork Reduction Act petition. Telephone conversation with Robert Niemann, Center for Medicare and Medicaid Services (Sept. 4, 2001).

fee schedule for services of physicians, the Health Care Financing Administration, now the Center for Medicare and Medicaid Services, decided not to include these drugs in a fee schedule, but rather to make a separate payment for each drug and require carriers to use a consistent method of payment. *Id.*

The notice indicated that some studies by the Office of Inspector General of the Department of Health and Human Services investigating the Medicaid program had led HCFA to believe that the *Red Book* and other wholesale price guides "substantially overstate the true cost of drugs." *Id.*[2] According to these studies, pharmacies were getting an average discount of 15.9% off the published wholesale price and HCFA had no reason to believe that physicians paid higher prices than pharmacies paid. *Id.* The agency proposed instructing carriers to base payment for incident to drugs on 85% of the national average wholesale price (as published in the *Red Book* and similar price listings). For very high volume drugs, HCFA proposed limiting payment to the lower of the estimated acquisition cost for the drug as determined by HCFA and specified in instructions to carriers, or 85% of the national average wholesale price of the drug. *Id.* The proposed regulation for payment of incident to drugs appeared at section 415.34 of title 42 of the Code of Federal Regulations. *Id.* at 25801. *See id.* at 25860 for the text of the proposed regulation.

HCFA proposed this payment policy under authority of section 1842(b)(8) of the Social Security Act, 42 U.S.C. § 1395u(b)(8), which authorizes it by regulation to establish a limit on a charge based on inherent reasonableness if it has determined that a charge is grossly excessive. *See* 42 C.F.R. § 405.502(g)(1)(vi). 56 *Fed. Reg.* at 25800.

In the notice of final rules published in November of 1991, HCFA modified its proposed policy of basing payment for drugs on 85% of the national AWP of the drug and for high volume drugs on the lower of the estimated actual acquisition costs as determined by HCFA and specified in instructions to carriers, or 85 percent of the national AWP. Instead of 85% of the average wholesale price, HCFA decided to base payment for these drugs on the lower of the national AWP, *i.e.*, 100% of AWP, or the Medicare carrier's estimate of actual acquisition costs. 56 *Fed. Reg.* 59525 (Nov. 25, 1991). HCFA published the final regulation at 42 C.F.R. §§ 415.36 (Payment for drugs incident to a physician's service) and 405.517 (Payment for drugs and biologicals that are not paid on a cost or prospective payment basis). *Id. See id.* at 59627 and 59621, respectively, for the texts of the final regulations.

HCFA explained that because there can be many wholesale prices listed for each drug from multiple sources, it defined the national AWP as the median price for all sources of the generic form of the drug. Estimated acquisition costs would be based on individual carrier estimates of the costs that physicians or other providers, as appropriate, actually pay for the drugs. For certain types of drugs, such as chemotherapy drugs, significant indirect costs such as inventory costs, waste, and spoilage could be considered by carriers if those costs were documented. *Id.* at 59525

HCFA elaborated that many comments, primarily from oncologists, submitted in response to the proposed regulation indicated that the 85% of AWP standard was

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[2] *See* State of Louisiana v. United States Department of Health and Human Services, 905 F.2d 877 (5th Cir. 1990), which affirmed HCFA's denial of a state request to use the AWP for Medicaid reimbursement on the ground that it exceeded estimated actual costs, for a discussion of the widespread state use of the AWP as a primary or significant measure of the estimated acquisition cost prior to this denial and the Inspector General's audit of six states.

inappropriate. Commenters observed that many drugs, particularly multisource drugs, could be purchased for considerably less than 85% of AWP, while others were not discounted. Other commenters suggested that while pharmacies and large medical practices could receive substantial discounts on their drug purchases, individual physicians could not. "The bulk of the comments suggesting alternatives to our proposal indicated that the amounts paid should be based on actual or estimated acquisition costs." *Id.* at 59524.

Many oncologists suggested that an add-on should be provided in the final regulation to account for the cost of breakage, wastage, shelf-life limitations, and inventory costs associated with chemotherapy agents. Some commenters said that an add-on payment was needed to account for shortfalls in chemotherapy administration payments and that if oncologists did not receive adequate compensation, many physicians would perform the service in hospital outpatient departments at substantially higher costs. Some said that physicians might refuse to supply the drugs to patients, forcing patients to purchase the drugs themselves and bring them to the physician's office to be administered. In the latter case, the drugs would not be covered by Medicare because the physician did not incur any costs for the drugs. *Id.*

Congress revised the reimbursement rate for incident to drugs and biologicals in section 4556 of the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, 462-463 (1997). Section 4556 amended section 1842 of the Social Security Act, 42 U.S.C. § 1395u, by adding subsection (o).

> (o)(1) If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part [Part B] and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is equal to 95 percent of the average wholesale price.
>
> (2) If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part, the Secretary may pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy.

This change was to take effect on January 1, 1998.

Section 4556 also directed the Secretary of Health and Human Services to study the effect of this amendment on the average wholesale price of drugs and biologicals and report to the Committees on Ways and Means and Commerce of the House and the Committee on Finance of the Senate the results of the study not later than July 1, 1999.

The joint explanatory statement said that the conference managers included the House provision, which provided that payment would equal 95% of the average wholesale price, with modifications. The specific modifications were that if payment was made to a licensed pharmacy, the Secretary of Health and Human Services, as the Secretary found appropriate, would pay a dispensing fee (less applicable deductible and coinsurance amounts) and that the Secretary should conduct a study of the effect of the provision on the average wholesale prices and report findings to congressional committees. H. Rep. No. 217, 105th Cong., 1st Sess. 798 (1997).

Sections 10616 and 4616 of the House bills had recommended that in any case where payment was not made on a cost or prospective basis, payment would equal 95% of the average wholesale price and that the change should apply to drugs and biologicals furnished on or after January 1, 1998.

Section 5526 of the Senate bill had recommended a similar provision, except that the average wholesale price would have been "as determined by the Secretary." It added that beginning in 1998, the payment amount could not exceed the amount payable on May 1, 1997, and in subsequent years, it could not exceed the previous year's amount increased by the percentage increase in the Consumer Price Index. For any other drug or biological, the annual increase for any year following the first year for which payment is made would be limited to the percentage increase in the CPI. If payment was made to a licensed pharmacy, the Secretary (as the Secretary determined appropriate) would pay a dispensing fee (less applicable deductible and insurance amounts). It also required the Secretary to conduct studies and surveys as necessary to determine the average wholesale price (and such other prices the Secretary determined appropriate) and report the results to appropriate congressional committees within six months of enactment.

To conform to the 1997 statutory change, HCFA proposed revising section 415.517 of title 42 of the Code of Federal Regulations, which relates to payment for drugs and biologicals not on a cost or prospective payment basis. Drugs and biologicals paid on this basis are not only those furnished incident to a physician's service, but also drugs furnished by pharmacies under the durable medical equipment (DME) benefit, and drugs furnished by independent dialysis facilities that are not included in the end-state renal disease (ESRD) composite rate payment. 63 *Fed. Reg.* 30846 (June 5, 1998).

HCFA proposed eliminating the estimated acquisition cost (EAC), which had been one basis for payment, the other being 100% of the average wholesale price (AWP), and paying at the lower of the actual charge on the Medicare claim or 95 percent of AWP. HCFA also proposed revising the method of calculating the average wholesale price. Regulations then in effect provided that for multiple source drugs, the AWP was equal to the median AWP of the generic forms of the drug. The AWP for the brand name products was ignored on the presumption that the brand AWP always was higher than the generic AWPs. HCFA said that while this presumption may have been true when the policy first was promulgated in 1991, it was not always true in 1998. Consequently, it proposed that the AWP for multiple source drugs would be equal to the lower of the median price of generic AWPs or the lowest brand name AWP. *Id. See id.* at 30878 for the text of the proposed regulation, 42 C.F.R. § 517 (Payment for drugs and biologicals that are not paid on a cost or prospective payment basis).

The final rule adopting HCFA's proposed rule with modifications was published on November 2, 1998. The charge allowed by Medicare for drugs and biologicals would be the lower of 95 percent of the median generic AWP or 95 percent of the lowest brand AWP. A brand product was defined as a product marketed under a labeled name that is other than the generic chemical name of the drug or biological. The allowed charge for drugs and biologicals that do not have an AWP would be determined by the local Medicare contractor based on prices paid by physicians and suppliers who use them. 63 *Fed. Reg.* 58850 (Nov. 2, 1998). *See id.* at 58905 for the text of the final rule, 42 C.F.R. § 405.517.

In section 4316 of the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, 390-391 (1997), Congress amended paragraphs (8) and (9) of section 1842(b) of the Social Security Act, 42 U.S.C. § 1395u(b). The amendment authorizes the Secretary of Health and Human Services, by regulation, to describe factors to be used in determining the cases of

items or services in which application of Part B (other than physicians' services) results in the determination of an amount that, because of its being grossly excessive or grossly deficient, is not inherently reasonable, and to provide in those cases for factors to be considered in determining an amount that is realistic and equitable. Notwithstanding such a determination, the Secretary may not apply factors that would increase or decrease a payment under Part B during any year for any particular item or service by more than 15 percent from such payment during the preceding year unless certain determinations are made.

Without issuing a notice of proposed rulemaking, HCFA issued an interim final rule implementing inherent reasonableness authority by amending section 405.502 of title 42 of the Code of Federal Regulations. 63 *Fed. Reg.* 687 (Jan. 7, 1998). The authority applied the inherent reasonableness standard to all Part B services, other than services of physicians, described in section 1861(s) of the Social Security Act, 42 U.S.C. § 1396x(s), which appears to include drugs furnished as an incident to a physician's professional service. *See id.* at 689-690 for the text of section 405.502 (Criteria for determining reasonable charges).

Late in 1998, HCFA reportedly attempted to use the inherent reasonableness authority, as amended by section 4316 of the Balanced Budget Act, to reduce what it considered excessive reimbursement for several items. One item, albuterol, a drug used with a nebulizer to treat patients suffering from asthma and emphysema under the durable medical equipment (DME) benefit, reportedly was targeted for an 11 percent fee reduction. Office of the Inspector General, Department of Health and Human Services, *Medicare Reimbursement for Prescription Drugs*, OEI-00-00310, 2 (Jan. 2000).

Congress suspended the inherent reasonableness authority in section 223 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, contained in the Consolidated Appropriations Act, Fiscal Year 2000, Pub. L. No. 106-113, 113 Stat. 1501A-352-353 (1999), until the General Accounting Office released a report and the Secretary of Health and Human Services published a notice of final regulations that responded to comments received in response to the January interim final regulation. The General Accounting Office issued its report on July 5, 2000, and reportedly found that inherent reasonableness reductions for some items were justified, but questioned the methodology that durable medical equipment regional carriers (DMERCs) used to collect pricing data for albuterol sulfate. *Id.* at 2-3.

The joint explanatory statement of conference managers explained that the House bill, H.R. 3075, 106th Cong., 1st Sess., prohibited the Secretary from exercising inherent reasonableness authority until afer the Secretary had issued a final rule, which must be preceded by a new proposed rulemaking and a minimum 60 day public comment period. The Senate bill, S. 1788, 106th Cong., 1st Sess., prohibited the Secretary from using this authority until 90 days after the General Accounting Office issued a report on this issue. H. Rep. No. 479, 106th Cong., 1st Sess. 876-877 ((1999).

The conference agreement included elements of both House and Senate provisions with modifications to prohibit the Secretary from using this authority until after GAO issued a report on the Secretary's recent use of that authority and the Secretary published a notice of a final rule in the *Federal Register* that responded to the report and to comments received in response to the Secretary's interim final regulations published on January 7, 1998. *Id.* The conference managers believed that inherent reasonableness authority should be administered judiciously and applied only after public concerns and suggestions about proposed administrative criteria have been addressed openly. Moreover, the rule should include an

explanation of the Secretary's costing methodology which should be based on statistically reliable and relevant data. *Id.*

Some actions before and after enactment of the Balanced Budget Act merit attention. The Administrator of HCFA, Nancy-Ann Min DeParle, indicated to Congress that she was considering whether to change from a reimbursement system based on AWP to one based on physician acquisition costs, but Congress reportedly did not accept this proposal in 1997 and 1998. In 1999, the Clinton administration proposed that HCFA pay 83 percent rather than 95 percent of the AWP, a reduction that HCFA actuaries estimated would save the program $2.9 billion over ten years. Bureau of National Affairs, *Health Care Daily*, vol. 5, no. 107 (June 2, 2000).

In May of 2000, HCFA reportedly announced plans to use newly available AWPs developed for Medicaid by the Department of Justice and the National Association of Medicaid Fraud Control Units. Bureau of National Affairs, *Health Care Daily*, vol. 5, no. 107 (June 2, 2000). It formally informed intermediaries and carriers in September of 2000 to begin using these alternative AWPs for 32 listed drugs which accounted for an estimated 75% of Medicare spending, but not for 14 chemotherapy drugs and three clotting factors. Health Care Financing Administration, Department of Health and Human Services, Program Memorandum Intermediaries/Carriers, Transmittal No. AB-00-86 (Sept. 8, 2000).

Two months later, HCFA notified intermediaries and carriers that they should *not* use Department of Justice data attached to the September 8 program memorandum and added that, "While we continue to believe that the AWPs reported in the usual commercially available sources are inaccurate and inflated above the true wholesale prices charged in the marketplace, congressional action may preclude the use of this alternative source. To avoid the disruption that would result from a decrease in payment allowances followed by an immediate increase due to final congressional action, we are deferring use of the DOJ AWP data until further notice." HCFA, DHHS, Program Memorandum Intermediaries/Carriers, Transmittal No. AB-00-115 (Nov. 17, 2000).

Shortly thereafter, Congress passed section 429 of the Benefits Improvement and Protection Act (BIPA) as part of the Consolidated Appropriations Act of 2000, Pub. L. No. 106-554, 114 Stat. 2763A-522-524 (2000). Section 429 directs the Comptroller General, the head of the General Accounting Office, to study reimbursement for drugs and biologicals under the current methodology pursuant to section 1842(o) of the Social Security Act, 42 U.S.C. § 1395u(o), and for related services under Part B of title XVIII. In the study, the Comptroller General is required to identify average prices at which such drugs are acquired by physicians and other suppliers, quantify the difference between such average prices and the reimbursement amount under that section, and determine the extent to which (if any) payment under Part B is adequate to compensate physicians, providers of services, or other suppliers for costs incurred in administering, handling, or storing such drugs. Not later than nine months after the date of enactment (December 21, 2000 was the enactment date) the Comptroller General is required to submit to Congress and the Secretary of Health and Human Services a report on the study and recommendations for revised payment methodologies.

In addition, section 429 also charges the Comptroller General with providing specific recommendations for revised payment methodologies for reimbursing drugs and for related services under Medicare, including an adjustment under section 1848(c) of the Social Security Act, 42 U.S.C. § 1395w-4(c). Specific recommendations also should be provided for the practice expense component of the physician fee schedule for costs incurred in

administering, handling, or storing certain categories of drugs and proposals for new payments to providers of services or suppliers for such costs, if appropriate.

Section 429 mandates that the Secretary of Health and Human Services, notwithstanding any other provision of law, should revise the payment methodology for drugs based on recommendations contained in the report of the Comptroller General. To the extent that the Secretary determines appropriate, the Secretary may provide for adjusting payments for the practice expense component and for new payments to providers of services or suppliers, but in no case may the estimated aggregate payments for drugs under the revised system, including for additional payments, exceed the aggregate amount of payment for such drugs, as projected by the Secretary, that would have been made under the payment methodology in effect under section 1842, *i.e.*, 95 percent of AWP.

The section also imposes a moratorium, effective for drugs furnished on or after January 1, 2001, on any direct or indirect decrease in reimbursement for drugs under the current payment methodology until the Secretary has reviewed the report of the Comptroller General. *See* H. Rep. No. 1033, 106th Congress, 2d Session 514 (2000) for iteration of section 429 in the joint explanatory statement.

During this moratorium, *i.e.*, before completion of the report of the Comptroller General, HCFA notified intermediaries and carriers that while the moratorium prohibited lowering a payment allowance based on a change in methodology, *e.g.*, reducing a rate from 95 percent of AWP to 90 percent or using an alternative source for AWP, the agency believed that it did not apply to any change in payment allowance resulting from marketplace factors. For example, if reimbursement was based on 95 percent of the AWP for a single source brand name product and a new generic form of the product should became available at a lower AWP, a new lower payment allowance based on 95 percent of the new lower priced generic would result. A similar reduction would result from a manufacturer lowering its AWP for a product as reflected in a subsequent issue of a carrier's usual source of AWP. HCFA, DHHS, Program Memorandum Intermediaries/Carriers, Transmittal AB-01-66 (May 3, 2001)

Conclusion

This memorandum has provided a chronicle of regulatory and legislative developments regarding use of the average wholesale price as the basis for Medicare Part B reimbursement of drugs that cannot be self-administered and are furnished incident to a physician's professional service. The AWP appears in guides such as *Drug Topics Red Book*, *Price Alert*, and *Medispan* and is based on prices submitted to publishers by drug manufacturers, suppliers, and distributors. In 1991, the Health Care Financing Administration adopted a fee schedule for services of physicians, but chose not to include these drugs in that schedule. Instead, it decided to pay for the drugs themselves and require carriers to use a consistent method of payment. Prior to this time, some carriers had been paying for these drugs on the basis of estimated acquisition costs to physicians using the *Red Book* or other wholesale price guides while others used actual acquisition costs determined in carrier surveys.

In June of 1991, HCFA proposed reimbursement at the rate of 85% of AWP based on studies of the Medicaid program by the Inspector General of the Department and Health and Human Service which indicated that pharmacies were receiving discounts of about 15% from the prices listed in the guides and on HCFA's belief that physicians were receiving similar discounts. In November of 1991, HCFA modified its proposal to require, beginning on January 1, 1992, reimbursement at the lower of the estimated acquisition cost or 100% of

AWP. The estimated acquisition cost was to be determined from surveys of actual invoice prices paid for each drug, taking into account factors such as inventory, waste, and spoilage. Reimbursement for multiple source drugs was to be based on the lower of the estimated acquisition cost or the wholesale price defined as the median price for all sources of the generic form of a drug.

Following a number of studies primarily by the Inspector General which indicated that Medicare may have been overpaying for drugs, Congress reduced the reimbursement rate to 95% of AWP in the Balanced Budget Act of 1997. HCFA in 1998 issued regulations implementing this statutory change by eliminating the estimated acquisition cost as a basis for reimbursement and by clarifying that the allowed charge would be the lower of 95 percent of the median generic AWP or 95% of the lowest brand AWP.

Congress in the Balanced Budget Act of 1997 also authorized the Secretary of Health and Human Services, acting through HCFA, to diverge from a statutorily defined payment method if the Secretary found that such method resulted in payment amounts that were not inherently reasonable and to issue regulations to adjust payments by 15% above or below the rate set pursuant to statute.

In January of 1998, shortly after the Balanced Budget Act was enacted, HCFA, without issuing notice of proposed rulemaking, published an interim final regulation expressing the agency's understanding of this expanded inherent reasonableness authority. Late in 1998, the agency reportedly attempted to use this authority to reduce payment for some drugs, including albuterol, which is used with a nebulizer for asthma and emphysema under the durable medical equipment (DME) benefit.

Congress responded to this attempt in the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 by suspending exercise of the inherent reasonableness authority until the Comptroller General, who heads the General Accounting Office, could conduct a study of the standards being used to determine inherent reasonableness. The Comptroller General in July of 1999 reportedly concluded that reductions based on inherent unreasonableness for some drugs were justified, but questioned the methodology that carriers used to collect pricing data for some drugs.

The Clinton administration in 1999 reportedly proposed reducing reimbursement for some drugs from 95% to 83%. The HCFA Administrator notified Congress that Inspector General and Department of Justice studies indicated that Medicare was overpaying for drugs and that she was considering whether to base reimbursement on estimated acquisition costs rather than the AWP. In May of 2000, HCFA reportedly announced plans to use newly available AWPs for Medicare that had been developed for Medicaid by the Department of Justice and the National Association of Medicaid Fraud Control Units. It informed carriers and intermediaries to use these new AWPs for 32 listed drugs, but not for 14 chemotherapy drugs and 3 clotting factors in September of 2000, but reversed this directive in November, two months later, saying that congressional action was anticipated.

Shortly thereafter, Congress imposed a moratorium on any reductions in reimbursement levels in the Benefits Improvement and Protection Act (BIPA) and directed the Comptroller General to study reimbursement of drugs including the medical practice component and to report findings to Congress and the Secretary of Health and Human Services in late August or early September of 2001. It also mandated that the Secretary should revise the payment methodology based on recommendations of the Comptroller General.

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Selected HHS Office of Inspector General Reports

Medicare and Medicaid Prescription Drug Reimbursement

1992 through June 2000

June 2000. Medicare Reimbursement of End Stage Renal Disease (ESRD) Drugs (OEI-03-00-00020 6/00). This inspection compares Medicare payment amounts for end stage renal disease drugs with amounts paid by Medicaid and the Department of Veterans Affairs. The OIG found that Medicare allowed amounts would be nearly halved for 5 ESRD drugs if amounts were based on VA acquisition costs and Medicare would save between 5 and 38 percent for 5 ESRD drugs if its allowed amounts were equal to Medicaid reimbursement including rebates.

June 2000. Medicare Reimbursement of Albuterol (OEI-03-00-00311). This report compares the amount Medicare pays for Albuterol with (1) the amounts reimbursed by Medicaid and the Department of Veterans Affairs, and (2) prices available at pharmacies. The OIG found that the Medicare reimbursement amount for albuterol is almost seven times greater than the VA price and is almost double Medicaid's upper limit of $0.24 per mg. (Note: Prior to 1998, HCFA based payments on milliliters, then changed to milligrams.) Prices at pharmacies ranged from a low of $0.24 per mg to a high of $0.48 per mg for a single box supply. At the median price of $0.38 per mg, Medicare and its beneficiaries could save $47 million per year. If adjusted to the Medicaid level, Medicare could save $120 million per year, and, if adjusted to the amount available to the VA under the Federal Supply Schedule, Medicare could save $209 million per year.

November 1998. Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs (OEI-03-97-00293). This report compares Medicare allowances for prescription drugs with drug acquisition prices currently available to the Department of Veterans Affairs. The OIG found that Medicare and its beneficiaries could have saved $1 billion in 1998 if the allowed amounts for 34 drugs had been equal to prices obtained by the VA. Medicare allowed between 15 and 1600 percent more than the VA for the 34 drugs reviewed.

August 1998. The Impact of High-Priced Generic Drugs on Medicare and Medicaid OEI-03-97-00510). This report determines the impact of high-priced generic drugs on the Medicare and Medicaid programs. The OIG found that Medicare and its beneficiaries could have saved $5 million to $12 million for four drugs if 1997 reimbursement had not been based on higher-priced generic versions. Florida's Medicaid program could have saved half a million dollars for just 8 drugs in 1996 if higher-priced generic drugs had been reimbursed at brand prices.

May 8, 1998. Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs (A-06-97-00052). The OIG recommended that the Health Care Financing Administration develop and submit a legislative proposal to the Congress that would require drug manufacturers participating in the Medicaid outpatient prescription drug program to pay Medicaid drug rebates based on AWP. The HCFA did not concur, stating that they did not believe such legislation would be feasible at that time. The HCFA did agree, however, that changing from the average manufacturers price (AMP) to AWP would reduce the administrative burden involved in the AMP calculations, and that they are planning a comprehensive study of AWP.

December 1997. Excessive Medicare Payments for Prescription Drugs (OEI-03-97-00290). This report compares Medicare allowances for prescription drugs with drug acquisition prices currently available to the physician and supplier communities. The OIG found that Medicare allowances for 22 drugs exceeded actual wholesale prices by $447 million in 1996. That amount could have been saved if actual wholesale prices, rather than Average Wholesale Price (AWP) had been the basis for reimbursement. For more than one-third of the 22 drugs reviewed, Medicare allowed amounts were more than double the actual wholesale prices available to physicians and suppliers. The OIG also

found there was no consistency among carriers in establishing and updating Medicare drug reimbursement amounts.

August 4, 1997. Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products (A-06-97-00011). The OIG estimated that, on average, actual acquisition cost of generic drugs was 42.5 percent below AWP. Unlike brand name drugs, where reimbursement is predominantly based on a discounted AWP, reimbursement of generic drugs can be limited by Federal upper limit amounts that are established by HCFA. Taking the upper limits into consideration, the OIG calculated a savings of as much as $145.5 million in Calendar Years (CY) 1994 and 1995 for 200 generic drugs with the greatest amount of Medicaid reimbursement in each year, if reimbursement had been based on the findings of this report.

April 10, 1997. Medicaid Pharmacy: Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs (A-06-96-00030). The OIG estimated that actual acquisition cost was a national average of 18.3 percent below AWP. This estimate combined the results for four categories of pharmacies including rural-chain, rural-independent, urban-chain, and urban-independent and excluded the results obtained from non-traditional pharmacies. Using the results of its review, the OIG calculated that as much as $225 million could have been saved for 100 drugs with the greatest amount of Medicaid reimbursements in Calendar Year 1994, if reimbursement had been based on the findings of this report.

June 1996. A Comparison of Albuterol Sulfate Prices (OEI-03-94-00392). This report assesses the appropriateness of the amount Medicare allows for albuterol sulfate a prescription inhalation drug used in nebulizers. The OIG found that fifty-five percent of retail pharmacy stores charged less for generic versions of albuterol sulfate than the $0.43 per milliliter that Medicare allowed. The generic drug prices that five buying groups negotiated ranged from 56 to 70 percent less than the Medicare allowed amount.

June 1996. Suppliers' Acquisition Costs for Albuterol Sulfate (OEI-03-94-00393). The OIG found that suppliers paid an average cost of $0.19 per milliliter to purchase albuterol sulfate, while Medicare's allowed amounts ranged from $0.40 to $0.43 per ml during the 14-month period of review. Medicare could have saved $94 million over the 14 months if albuteral sulfate allowances had been based on the average of supplier invoice costs.

May 1996. Appropriateness of Medicare Prescription Drug Allowances (OEI-03-95-00420). This report assesses the appropriateness of Medicare Part B allowances for prescription drugs through a comparison with Medicaid reimbursement mechanisms. The OIG found that under a drug rebate program similar to Medicaid's, Medicare would have saved 14.6 percent ($122 million) of its allowances for 17 drugs in 1994. Medicare could also have saved $144 million in 1994 had to program employed a discounted AWP drug reimbursement formula like many Medicaid States. However, the lack of a national drug code-based billing system would prevent HCFA from taking advantage of manufacturer drug rebates and other discounted reimbursement formulas.

February 1996. Payments for Prescription Drugs Used with Nebulizers (OEI-03-94-00390; 2/96). This report examines differences in the reimbursement methodologies used by the Medicare and Medicaid programs to pay for prescription drugs, focusing on three inhalation drugs used in nebulizers (Albuterol Sulfate and Metaproterenol .4 and .6 percent). The OIG projected that if Medicare had revised its payment methodologies and implemented a rebate program (such as the Medicaid program has), Medicare and its beneficiaries could have saved $58 million of the $226 million that was allowed for nebulizer drugs (excluding administrative costs) in 1994.

July 7, 1994. Medicaid Program Savings Through the Use of Therapeutically Equivalent Generic Drugs (A-06-93-00008 - OEI-03-94-00080). Joint audit/inspection report. For just 37 high volume brand name drugs, the OIG estimated annual cost savings to the Medicaid program could be as much as $46 million if the reimbursement for those drugs is limited to the amounts set by HCFA for

equivalent generic drugs. The cost savings would become even greater in the future as the Federal patents on exclusive drug manufacturing of 60 highly used brand name drugs with more than $10 billion in sales expire between now and 1995.

April 23, 1992. Medicaid Drug Rebates: Improvements Needed in the Health Care Financing Administration's Procedures to Implement the Medicaid Drug Rebate Program (A-06-91-00102). The OIG review identified 200 different drug codes in three states involving 22 different drug manufacturers where errors in the average manufacturers' price, base AMP and best price resulted in URAs being overstated. Also, some States did not successfully meet the July 30, 1991 billing deadline for billing manufacturers under the Medicaid drug program.

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APPENDIX E

Medicare Savings Based on Physician/Supplier Costs

HCPCS CODE	GENERIC DRUG NAME	MEDICARE MEDIAN	CATALOG MEDIAN	PERCENT SAVINGS*	1999 ALLOWED CHARGES	ESTIMATED MEDICARE SAVINGS
J0640	Leucovorin Calcium, 50 mg	$18.02	$2.94	83.7%	$66,740,227	$55,851,422
J1260	Dolasetron Mesylate, 10 mg	$14.82	$8.29	44.1%	$46,647,272	$20,553,758
J1440	Filgrastim, 300 mcg	$171.38	$144.30	15.8%	$47,893,675	$7,567,748
J1441	Filgrastim, 480 mcg	$273.03	$229.90	15.8%	$67,411,261	$10,648,821
J1562	Immune Globulin, 5g	$396.63	$300.00	24.4%	$43,239,398	$10,534,309
J1626	Granisetron HCl, 100 mcg	$18.54	$13.81	25.5%	$46,432,246	$11,845,983
J2405	Ondansetron HCl, 1 mg	$6.09	$5.49	9.9%	$47,721,885	$4,701,664
J2430	Pamidronate Disodium, 30 mg	$243.56	$223.26	8.3%	$112,916,846	$9,411,283
J2820	Sargramostim, 50 mcg	$27.41	$23.13	15.6%	$23,533,251	$3,674,656
J7608	Acetylcysteine, per g	$5.05	$3.38	33.1%	$35,908,222	$11,874,600
J7619	Albuterol Sulfate, per mg	$0.47	$0.13	72.3%	$246,136,877	$178,056,464
J7644	Ipratropium Bromide, per mg	$3.34	$1.53	54.2%	$250,916,635	$135,975,781
J9000	Doxorubicin HCl, 10 mg	$42.92	$10.08	76.5%	$27,831,805	$21,295,351
J9045	Carboplatin, 50 mg	$101.37	$87.79	13.4%	$116,254,013	$15,573,932
J9170	Docetaxel, 20 mg	$283.65	$238.86	15.8%	$58,661,193	$9,262,947
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.49	15.8%	$75,256,901	$11,884,907
J9202	Goserelin Acetate, 3.6 mg	$446.49	$375.99	15.8%	$321,485,273	$50,761,969
J9206	Irinotecan, 20 mg	$117.81	$98.63	16.3%	$79,914,022	$13,010,364
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$499.03	15.8%	$620,102,889	$97,912,635
J9265	Paclitaxel, 30 mg	$173.49	$146.10	15.8%	$249,940,717	$39,459,774
J9310	Rituximab, 100 mg	$420.29	$353.93	15.8%	$71,072,780	$11,221,751
J9350	Topotecan, 4 mg	$573.75	$507.32	11.6%	$31,504,581	$3,647,668
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$64.11	15.1%	$24,325,270	$3,669,733
Q0136	Epoetin Alfa, per 1000 units	$11.40	$10.72	6.0%	$379,708,697	$22,649,291
TOTAL FOR 24 HCPCS					$3,091,555,936	$761,046,810

* To determine percent savings, we subtracted the catalog price from the Medicare reimbursement amount. We then divided this number by the Medicare reimbursement amount.

Estimated Medicare Savings if Acquisition Costs Were Used for 1996 Prescription Drug Reimbursement

HCPCS Code	Drug Description	1996 Allowances	Estimated Savings	Percent Saved
J9217	Leuprolide Acetate	$577,547,780	$104,365,435	18%
J7620	Albuterol Sulfate 0.083%	$175,399,846	$92,199,355	53%
J9265	Paclitaxel	$125,093,980	$22,757,465	18%
J9202	Goserelin Acetate Implant	$84,187,487	$11,215,983	13%
J0640	Leucovorin Calcium	$57,323,221	$52,514,021	92%
J9045	Carboplatin	$67,530,797	$12,539,724	19%
J1440	Filgrastim, per 300 mcg.	$54,460,250	$11,592,740	21%
Q0136	Epoetin Alpha (Non-ESRD Use)	$79,558,670	$10,399,198	13%
J2405	Ondansetron Hydrochloride	$47,331,513	$14,319,348	30%
J1625	Granisetron Hydrochloride	$49,691,403	$13,399,842	27%
J1561	Immune Globulin	$35,104,622	$24,808,622	71%
J7670	Metaproterenol Sulfate 0.4%	$14,203,070	$9,935,367	70%
J1441	Filgrastim, per 480 mcg.	$40,592,257	$8,470,488	21%
J9182	Etoposide, 100 mg.	$25,739,111	$13,362,365	52%
J9000	Doxorubicin HCL, 10 mg.	$17,410,833	$12,480,751	72%
J9031	BCG (Intravesical)	$16,544,398	$2,682,097	16%
J9181	Etoposide, 10 mg.	$13,381,243	$5,909,155	44%
J7672	Metaproterenol Sulfate 0.6%	$6,595,854	$4,805,175	73%
J9293	Mitoxantrone Hydrochloride	$14,522,607	$2,712,650	19%
J9185	Fludarabine Phosphate	$15,462,970	$2,049,320	13%
J9010	Doxorubicin HCL, 50 mg.	$14,541,250	$10,513,722	72%
J3370	Vancomycin HCL	$8,234,140	$4,213,709	51%
TOTAL		$1,540,457,302	$447,246,532	29%

TABLE 3:

MEDICARE AND WHOLESALE CATALOGS
UNIT COSTS AND BENEFICIARY COINSURANCE

HCPCS CODE	GENERIC DRUG NAME	2000 MEDIAN PRICES		CATALOG PRICE AS PERCENTAGE OF MEDICARE PRICE	20% MEDICARE COINSURANCE	
		MEDICARE	CATALOGS		CURRENT	BASED ON CATALOG PRICE
J0640	Leucovorin Calcium, 50 mg	$18.02	$2.94	16.3%	$3.60	$0.59
J1260	Dolasetron Mesylate, 10 mg	$14.82	$8.29	55.9%	$2.96	$1.66
J1440	Filgrastim, 300 mcg	$171.38	$144.30	84.2%	$34.28	$28.86
J1441	Filgrastim, 480 mcg	$273.03	$229.90	84.2%	$54.61	$45.98
J1562	Immune Globulin, 5g	$396.63	$300.00	75.6%	$79.33	$60.00
J1626	Granisetron HCl, 100 mcg	$18.54	$13.81	74.5%	$3.71	$2.76
J2405	Ondansetron HCl, 1 mg	$6.09	$5.49	90.1%	$1.22	$1.10
J2430	Pamidronate Disodium, 30	$243.56	$223.26	91.7%	$48.71	$44.65
J2820	Sargramostim, 50 mcg	$27.41	$23.13	84.4%	$5.48	$4.63
J7608	Acetylcysteine, per g	$5.05	$3.38	66.9%	$1.01	$0.68
J7619	Albuterol Sulfate, per mg	$0.47	$0.13	27.7%	$0.09	$0.03
J7644	Ipratropium Bromide, per mg	$3.34	$1.53	45.8%	$0.67	$0.31
J9000	Doxorubicin HCl, 10 mg	$42.92	$10.08	23.5%	$8.58	$2.02
J9045	Carboplatin, 50 mg	$101.37	$87.79	86.6%	$20.27	$17.56
J9170	Docetaxel, 20 mg	$283.65	$238.86	84.2%	$56.73	$47.77
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.49	84.2%	$17.69	$14.90
J9202	Goserelin Acetate, 3.6 mg	$446.49	$375.99	84.2%	$89.30	$75.20
J9206	Irinotecan, 20 mg	$117.81	$98.63	83.7%	$23.56	$19.73
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$499.03	84.2%	$118.52	$99.81
J9265	Paclitaxel, 30 mg	$173.49	$146.10	84.2%	$34.70	$29.22
J9310	Rituximab, 100 mg	$420.29	$353.93	84.2%	$84.06	$70.79
J9350	Topotecan, 4 mg	$573.75	$507.32	88.4%	$114.75	$101.46
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$64.11	84.9%	$15.10	$12.82
Q0136	Epoetin Alfa, per 1000 units	$11.40	$10.72	94.0%	$2.28	$2.14

TABLE 4:

MEDICARE AND WHOLESALE CATALOGS:
POTENTIAL MEDICARE AND BENEFICIARY SAVINGS

HCPCS CODE	GENERIC DRUG NAME	2000 MEDIAN PRICES		PERCENT SAVINGS	2000 ALLOWED CHARGES	POTENTIAL SAVINGS		
		MEDICARE	CATALOGS			MEDICARE	BENEFICIARY	TOTAL
J0640	Leucovorin Calcium, 50 mg	$18.02	$2.94	83.7%	$69,228,203	$46,346,784	$11,586,696	$57,933,480
J1260	Dolasetron Mesylate, 10 mg	$14.82	$8.29	44.1%	$82,482,309	$29,074,736	$7,268,684	$36,343,420
J1440	Filgrastim, 300 mcg	$171.38	$144.30	15.8%	$51,133,657	$6,463,762	$1,615,941	$8,079,703
J1441	Filgrastim, 480 mcg	$273.03	$229.90	15.8%	$83,837,285	$10,594,886	$2,648,721	$13,243,607
J1562	Immune Globulin, 5g	$396.63	$300.00	24.4%	$49,903,101	$9,726,217	$2,431,554	$12,157,771
J1626	Granisetron HCl, 100 mcg	$18.54	$13.81	25.5%	$42,674,561	$8,709,846	$2,177,461	$10,887,307
J2405	Ondansetron HCl, 1 mg	$6.09	$5.49	9.9%	$55,003,100	$4,335,220	$1,083,805	$5,419,025
J2430	Pamidronate Disodium, 30 mg	$243.56	$223.26	8.3%	$156,095,768	$10,408,094	$2,602,023	$13,010,117
J2820	Sargramostim, 50 mcg	$27.41	$23.13	15.6%	$27,758,142	$3,467,489	$866,872	$4,334,361
J7608	Acetylcysteine, per g	$5.05	$3.38	33.1%	$22,452,105	$5,939,804	$1,484,951	$7,424,756
J7619	Albuterol Sulfate, per mg	$0.47	$0.13	72.3%	$261,270,168	$151,203,161	$37,800,790	$189,003,951
J7644	Ipratropium Bromide, per mg	$3.34	$1.53	54.2%	$310,310,047	$134,529,625	$33,632,406	$168,162,031
J9000	Doxorubicin HCl, 10 mg	$42.92	$10.08	76.5%	$30,586,166	$18,722,268	$4,680,567	$23,402,835
J9045	Carboplatin, 50 mg	$101.37	$87.79	13.4%	$140,046,625	$15,009,041	$3,752,260	$18,761,302
J9170	Docetaxel, 20 mg	$283.65	$238.86	15.8%	$110,792,891	$13,995,878	$3,498,970	$17,494,848
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.49	15.8%	$100,322,242	$12,674,671	$3,168,668	$15,843,338
J9202	Goserelin Acetate, 3.6 mg	$446.49	$375.99	15.8%	$375,955,270	$47,490,150	$11,872,538	$59,362,688
J9206	Irinotecan, 20 mg	$117.81	$98.63	16.3%	$117,789,971	$15,341,391	$3,835,348	$19,176,739
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$499.03	15.8%	$633,720,145	$80,050,211	$20,012,553	$100,062,764
J9265	Paclitaxel, 30 mg	$173.49	$146.10	15.8%	$284,530,532	$35,936,556	$8,984,139	$44,920,694
J9310	Rituximab, 100 mg	$420.29	$353.93	15.8%	$135,054,269	$17,059,081	$4,264,770	$21,323,851
J9350	Topotecan, 4 mg	$573.75	$507.32	11.6%	$34,885,298	$3,231,275	$807,819	$4,039,094
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$64.11	15.1%	$27,866,679	$3,363,194	$840,799	$4,203,993
Q0136	Epoetin Alfa, per 1000 units	$11.40	$10.72	6.0%	$536,916,452	$25,621,276	$6,405,319	$32,026,595
TOTAL FOR 24 DRUGS					**$3,740,614,986**	**$709,294,617**	**$177,323,654**	**$886,618,271**

Comparison of VA Prices to Medicare Reimbursement Amounts for Selected Part B Injection and Infusion Drugs
OEI-03-01-00620

HCPCS CODE	DRUG	1998 VA	1998 CMS	SPREAD	1999 VA	1999 CMS	SPREAD	2000 VA	2000 CMS	SPREAD	2001 VA	2001 CMS	SPREAD
J0640	Leucovorin Calcium, 50 mg	$1.18	$20.45	$19.27	$1.63	$18.71	$17.08	$1.63	$18.02	$16.39	$1.99	$17.52	$15.53
J1260	Dolasetron Mesylate, 10 mg				$5.15	$14.24	$9.09	$4.95	$14.82	$9.87	$4.87	$15.82	$10.95
J1440	Filgrastim, 300 mcg	$106.69	$153.24	$46.55	$127.37	$167.04	$29.67	$130.72	$171.38	$40.66	$123.73	$173.72	$49.99
J1441	Filgrastim, 480 mcg	$169.55	$244.05	$74.51	$202.90	$250.14	$47.24	$208.23	$273.03	$64.80	$196.81	$285.38	$88.57
J1562	Immune Globulin, 5g	$110.83	$439.38	$328.55	$105.48	$425.12	$319.64	$110.54	$393.36	$282.82	$113.98	$413.25	$299.27
J1626	Granisetron HCl, 100 mcg	$8.42	$16.85	$8.43	$8.42	$16.85	$8.43	$7.81	$18.54	$10.73	$8.08	$18.54	$10.46
J2405	Ondansetron HCl, 1 mg	$2.43	$5.80	$3.37	$3.94	$5.81	$1.87	$3.94	$6.09	$2.15	$4.08	$6.09	$2.01
J2430	Pamidronate Disodium, 30 mg	$104.39	$196.90	$92.51	$166.59	$207.33	$40.74	$203.45	$243.56	$40.11	$173.51	$253.21	$79.70
J2820	Sargramostim, 50 mcg	$7.47	$21.49	$14.02	$10.06	$23.95	$13.89	$10.06	$27.41	$17.35	$10.06	$27.42	$17.36
J9000	Doxorubicin HCl, 10 mg	$7.46	$43.23	$35.77	$6.84	$43.25	$36.41	$6.29	$42.62	$36.63	$6.36	$43.23	$36.87
J9045	Carboplatin, 50 mg	$39.50	$84.16	$44.66	$40.09	$95.10	$55.01	$41.14	$101.37	$60.23	$42.56	$111.11	$68.55
J9170	Docetaxel, 20 mg	$148.07	$245.02	$96.95	$147.88	$257.29	$109.41	$151.77	$283.65	$131.88	$157.00	$297.83	$140.83
J9201	Gemcitabine HCl, 200 mg	$37.46	$75.15	$37.69	$37.58	$81.16	$43.58	$74.86	$88.46	$13.60	$77.45	$102.13	$24.68
J9202	Goserelin Acetate, 3.6 mg	$206.29	$389.98	$183.69	$209.36	$417.28	$207.92	$214.87	$446.49	$231.62	$154.91	$446.49	$291.58
J9206	Irinotecan, 20 mg	$75.45	$97.10	$21.65	$75.45	$104.84	$29.39	$75.45	$117.81	$42.36	$75.45	$125.48	$50.03
J9217	Leuprolide Acetate, 7.5 mg	$299.36	$513.60	$214.22	$297.89	$564.92	$267.03	$257.00	$592.60	$335.60	$227.21	$592.60	$365.39
J9265	Paclitaxel, 30 mg	$109.36	$173.50	$64.14	$110.99	$173.50	$62.51	$107.59	$173.49	$65.90	$107.93	$170.89	$62.96
J9310	Rituximab, 100 mg				$237.92	$400.28	$162.36	$239.58	$420.29	$180.71	$247.20	$441.30	$194.10
J9350	Topotecan, 4 mg	$299.35	$483.97	$184.62	$299.37	$520.93	$221.56	$307.25	$573.75	$266.50	$317.84	$632.65	$314.81
J9390	Vinorelbine Tartrate, 10 mg	$40.72	$61.47	$20.75	$45.01	$63.03	$18.02	$46.20	$75.50	$29.30	$47.80	$79.28	$31.48
Q0136	Epoetin Alfa, per 1000 units	$6.79	$12.00	$5.21	$7.11	$11.40	$4.29	$7.22	$11.40	$4.18	$7.39	$11.85	$4.46

* Code J1260 changed from 1 mg to 10 mg in 2000. In 1999, we calculated a price for 10 mg from the listed 1 mg price.

Medicare Allowed Charges for Selected Part B Injection and Infusion Drugs
OEI-03-01-00620

HCPCS CODE	DRUG	1998 ALLOWED CHARGES	1999 ALLOWED CHARGES	2000 ALLOWED CHARGES	1998 ALLOWED SERVICES	1999 ALLOWED SERVICES	2000 ALLOWED SERVICES
J0640	Leucovorin Calcium, 50 mg	$64,744,992	$67,175,585	$69,228,203	3,087,171	3,098,084	3,163,695
J1260*	Dolasetron Mesylate, 10 mg		$47,433,589	$82,482,309		32,079,369	8,309,669
J1440	Filgrastim, 300 mcg	$49,841,275	$48,392,363	$51,133,657	330,897	310,453	309,728
J1441	Filgrastim, 480 mcg	$57,551,703	$68,136,508	$83,837,285	249,785	276,073	316,750
J1562	Immune Globulin, 5g	$38,786,741	$44,081,836	$49,903,101	265,290	142,625	144,668
J1626	Granisetron HCl, 100 mcg	$46,133,312	$46,849,323	$42,674,561	2,727,860	2,662,312	2,334,230
J2405	Ondansetron HCl, 1 mg	$46,261,258	$48,075,083	$55,003,100	7,986,231	8,271,301	9,110,882
J2430	Pamidronate Disodium, 30 mg	$75,486,770	$114,573,719	$156,095,768	377,982	528,343	647,867
J2820	Sargramostim, 50 mcg	$17,203,115	$23,804,844	$27,758,142	740,033	953,239	1,041,938
J9000	Doxorubicin HCl, 10 mg	$30,220,312	$28,567,420	$30,586,166	717,728	736,113	733,873
J9045	Carboplatin, 50 mg	$98,057,972	$117,677,241	$140,046,625	1,109,100	1,252,177	1,409,185
J9170 *	Docetaxel, 20 mg	$37,471,267	$59,753,301	$110,792,891	148,832	225,449	398,565
J9201	Gemcitabine HCl, 200 mg	$47,225,063	$76,387,442	$100,322,242	634,608	914,109	1,106,717
J9202 *	Goserelin Acetate, 3.6 mg	$260,634,728	$322,817,323	$375,955,270	642,528	745,347	852,449
J9206 *	Irinotecan, 20 mg	$55,706,247	$81,056,351	$117,789,971	563,989	757,042	1,013,684
J9217 *	Leuprolide Acetate, 7.5 mg	$587,281,075	$622,883,124	$633,720,145	1,216,483	1,266,177	1,278,050
J9265	Paclitaxel, 30 mg	$206,261,616	$253,442,999	$284,530,532	1,200,900	1,477,268	1,665,594
J9310	Rituximab, 100 mg		$72,190,943	$135,054,269		187,717	325,024
J9350 *	Topotecan, 4 mg	$26,063,176	$31,814,926	$34,885,298	53,646	62,010	61,003
J9390	Vinorelbine Tartrate, 10 mg	$21,887,564	$24,584,308	$27,866,679	361,621	377,151	379,607
Q0136	Epoetin Alfa, per 1000 units	$212,643,312	$386,189,879	$536,916,452	18,307,564	32,924,548	46,146,497
TOTAL		**$1,979,461,498**	**$2,585,888,107**	**$3,146,582,666**	**40,722,248**	**89,246,907**	**80,749,675**

* Code J1260 Changed from 1 mg to 10 mg in 2000.

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Examination of the Prices That Medicare Pays for the Limited Number of Medicare-Covered Outpatient Drugs

May 5, 2000

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala:

I am writing to express my concerns over the excessive reimbursements that the Medicare program is paying for certain covered pharmaceuticals and other related products. Further, I wish to learn what actions the Health Care Financing Administration (HCFA) and the Department of Health and Human Services (HHS) have taken to address this problem.

As you know, the Office of Inspector General at HHS has issued a series of reports that have identified significant discrepancies between the prices Medicare pays for certain drugs and the prices that are available to private sector purchasers of these same drugs. In its December 1997 report, the Office of Inspector General (OIG) estimated that, in 1996 alone, Medicare could have saved $447 million by reducing the Medicare-allowed price for just 22 drugs to the actual prices available in the private wholesale sector. The OIG also found that Medicare could have saved at least 40 percent of the current allowance for almost half of the 22 drugs, and 93 percent for one particular drug, by limiting reimbursement to the available private sector prices for those drugs. As you know, Medicare is supposed to pay only 95 percent of the Average Wholesale Price (AWP) of these drugs under Federal law.

These findings are supported by additional investigative work that the Committee on Commerce has conducted. The Committee has written to several drug manufacturers, inquiring about the prices they charge to wholesale purchasers. The responses the Committee received confirmed that Medicare does in fact pay considerably more for certain drugs than the actual average price paid by such wholesalers. In addition, the Committee is continuing to investigate the practices of certain drug manufacturers relating to allegations that they manipulated the AWP of particular drugs in order to increase the sales of these drugs. I have enclosed for your review letters that the Committee has recently sent to several drug manufacturers regarding this investigation.

The information revealed in the OIG report and through the Committee's investigation is particularly troubling. I firmly believe that improper expenditures in the Medicare program, whether due to waste, abuse or fraud, are unacceptable. In the time that I have been Chairman of the Committee, we have held numerous hearings that have sought to prevent the payment of such improper expenditures throughout the Medicare and Medicaid programs. As Congress considers ways to expand the scope of Medicare's coverage of prescription drugs, it is essential that this Administration be able to assure Congress, the beneficiaries of the Medicare program, and the American people that it has done all that it can to prevent waste and abuse in the current limited Medicare drug program.

The December 1997 OIG report contained several specific recommendations relating to actions HCFA could take to address this problem, including requiring all Medicare carriers to reimburse a uniform allowed amount for each HCFA Common Procedure Coding System (HCPCS) drug code. In response to this report, then-Deputy Administrator Nancy-Ann Min DeParle wrote to the Inspector General, indicating that HCFA had convened a workgroup to develop an electronic file consisting of the AWPs for drugs covered by Medicare. She further stated that HCFA would then distribute this file to Medicare contractors for their use in paying claims for drugs.

To date, it appears that these efforts have not been implemented. The Committee has

learned that HCFA submitted a Request for Proposal to develop a solution to the problem of price variances between Medicare carriers, but no contract was ever entered into, and it does not appear that the issue has been resolved. The December 1997 OIG report noted, "[t]he rate at which physicians and suppliers are paid for drugs should not depend on which carrier providers bill." I strongly concur with this statement, and am deeply disturbed that it appears that HCFA has failed to remedy this problem in the two and a half years since it was first identified by the Inspector General.

In her response to the OIG report, then-Deputy Administrator Min DeParle also stated that HCFA would pursue other "appropriate ways" to eliminate the markup for drugs billed to Medicare, beyond those legislative initiatives contained in the President's budget. I understand that a rulemaking was initiated, but never completed, to utilize your authority to adjust Medicare reimbursements that are not inherently reasonable. I wish to learn by what other "appropriate ways" HCFA has attempted to address the problem of excessive reimbursements for Medicare-covered drugs. Accordingly, I request that, pursuant to Rules X and XI of the U.S. House of Representatives, you provide the following information to the Committee no later than May 26, 2000.

1. Please identify all actions taken by HCFA to date to independently investigate and assess the accuracy of the AWP as a measurement of wholesale drug prices.
2. Please identify all actions taken by HCFA to date to independently investigate and assess the discrepancies between the prices paid by Medicare and other non-governmental entities for Medicare-covered drugs.
3. Please identify the other "appropriate ways," mentioned in then-Deputy Administrator Min DeParle's response to the OIG report, that HCFA has utilized to address the problem of excessive reimbursements for Medicare-covered drugs. In your answer, please describe all actions that have been taken relating to these efforts.
4. Please identify whether the electronic file, also identified in then-Deputy Administrator Min DeParle's response to the OIG report, has been developed and is now operational. If the electronic file is not yet operational, please identify whether other actions have been taken to insure that all Medicare carriers are now reimbursing a uniform allowed amount for each HCPCS drug code.

If you should have any questions, please have your staff contact Mr. Charles Clapton, Committee Counsel, at (202) 226-2424. I appreciate your cooperation in this matter.

Sincerely,

Tom Bliley
Chairman

Attachments

cc: The Honorable John D. Dingell, Ranking Member

Response

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Medicare Drug Pricing Manipulation

CORRECTED VERSION

September 25, 2000

The Honorable Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Administrator Min DeParle:

I am writing in response to your September 8, 2000 letter, in which you announced that the Health Care Financing Administration ("HCFA") provided new pricing data to its Medicare carriers to limit excessive reimbursements for Medicare-covered drugs. I wish to express my concerns about the way in which the Administration has proceeded with respect to this matter and how these changes will be implemented. In addition, I am writing to bring to your attention very troubling information uncovered by a Committee on Commerce investigation strongly suggesting that certain drug manufacturers may be deliberately inflating the reported "average wholesale price" for their Medicare-covered drugs -- upon which Medicare reimbursement is set -- in order to increase the sales of their drugs.

HCFA has known for many years that it was paying inflated prices for certain drugs, yet the legislative proposals made by the Administration to remedy the problem have been deeply flawed, in part because they ignored the rampant price manipulations in which certain drug manufacturers have been engaged. It was refreshing to see that, through your action, HCFA and the Administration have at least acknowledged that they have a responsibility to protect Medicare and America's senior citizens from indiscriminate price gouging on certain pharmaceutical products. Your actions also demonstrate that HCFA already possesses -- and indeed has always possessed -- the authority to remedy this problem itself, without need of new legislation or any other Congressional action.

I remain deeply concerned, however, over the actions taken by the Administration to resolve this problem, which seem more intended to generate favorable media coverage than to respond to substantive public policy issues. Specifically, I refer to the correspondence I received from Health and Human Services Secretary Shalala on May 30, 2000, declaring that new pricing information would be provided to Medicare carriers in June of this year.

In subsequent meetings between my staff and HCFA representatives, it quickly became apparent that this announcement had been made without careful consideration of how these price changes would impact quality and access to care issues, and further that it would be impossible for HCFA to implement these changes within the time frame specified in Secretary Shalala's letter. I was hardly surprised, therefore, when I learned that HCFA had in fact failed to meet the Administration's own deadline. Obviously, the Administration had decided to declare a new policy without any meaningful

analysis beforehand.

On September 8, 2000, I received your letter indicating that HCFA finally had issued new pricing information to Medicare carriers, which could then be used to establish more accurate reimbursement rates that would take effect January 1, 2001. However, your letter specifies that this new pricing information will not be applied to certain drugs used in oncology and hemophilia treatments. As your letter also notes, payments for these drugs constitute 30 percent of Medicare's expenditures for covered drugs and 25 percent of the estimated savings that would result from any change in Medicare reimbursements. Yet, according to your letter, it has been determined that these particular drugs should be excluded from the proposed price change because of a conclusion by HCFA that "Medicare payments for services related to the provision of chemotherapy drugs and clotting factors used to treat hemophilia and similar disorders are inadequate." If this problem does indeed exist, it is one that HCFA should have been aware of and remedied long before I first wrote to Secretary Shalala, rather than tacitly allowing an alleged cross-subsidization between drug reimbursement rates and practice expenses to continue to exist. I am particularly disturbed by both HCFA's continuing failure to address this type of problem, and the practical consequences of such failure, which obstruct efforts to implement an accurate payment system for Medicare-covered drugs and cause further delay in giving financial relief to America's vulnerable Medicare beneficiaries.

In your September 8, 2000 letter, you also noted that HCFA will continue to gather more information relating to the reimbursements for certain drugs. In order to further this inquiry, I wish to share with you some of the information uncovered during the investigation that the Committee on Commerce has conducted into the setting of reimbursements for Medicare-covered drugs. To date, this investigation has revealed troubling patterns involving certain drug manufacturers, which appear to have deliberately manipulated the spreads between the prices they charge to providers and the Medicare reimbursement levels that are set based upon information they provide. These spreads, consisting of extra Medicare dollars available to providers, were in turn used to create profit-based incentives for providers to use a particular manufacturer's drug. This evidence shows that, in many instances, Medicare reimbursements -- which are based under Federal regulations upon the manufacturer- reported Average Wholesale Price (AWP) -- have little relationship to market-based prices, and have been used as a means to increase drug manufacturers' market share by providing improper financial incentives to health care providers.

The information obtained over the course of the Committee's investigation cumulatively demonstrates that the current reimbursement methodology for Medicare-covered drugs and HCFA's oversight of that program are so deeply flawed that they invite rampant abuse -- allowing drug manufacturers to essentially determine, as part of their sales and marketing strategies, how much particular health care provider groups will be reimbursed under Medicare. As a consequence of these critical flaws, Medicare and the senior citizens, disabled individuals and others who depend on Medicare to pay for certain drugs have paid billions of dollars in inflated drug prices.

As a result of what has been uncovered by the Committee's investigation, I am deeply fearful of proposals that rely upon an unreformed HCFA to administer an expanded drug benefit for all Medicare beneficiaries. Absent

significant reforms, such proposals can only result in the exponential growth of this type of abuse, with the inevitable loss of additional billions of scarce Medicare and Medicare beneficiary dollars. Such a course can be described only as reckless and irresponsible, given the rampant level of abuse that the Committee's investigation has uncovered to date in the limited drug benefit currently provided under Medicare. I support a drug benefit program that will help senior citizens pay the high costs of prescription drugs, but we must guarantee that the benefit will be structured in a way that does not result in similar price gouging of either the intended beneficiaries or the Medicare system itself.

The Committee began its investigation into the setting of Medicare reimbursements for covered drugs over one and a half years ago. Over the course of the investigation, the Committee contacted numerous drug manufacturers and requested information and internal documents relating to their sales and marketing practices for particular drugs. Committee staff reviewed almost 100,000 pages of internal documents from drug manufacturers relating to pricing, interviewed several drug manufacturer employees, and have been in contact with State and Federal investigators to obtain information relating to their pending inquiries into drug manufacturer practices and reimbursement issues generally.

By disclosing the inappropriate practices and other disturbing findings of this extensive Committee investigation, it is my hope that this information can be used to develop appropriate safeguards to protect Medicare and its beneficiaries from this type of abuse in the future. In order to further your efforts relating to this issue, I have summarized some of the information obtained in the course of the Committee's inquiries below, and attached several documents that shed greater light on the types of practices and abuses that the Committee has uncovered.

Scope of the Problem

Echoing the previous findings of numerous reports by the Department of Health and Human Services' Office of Inspector General (OIG), the Committee has uncovered substantial evidence that Medicare reimburses health care providers at prices dramatically more than what they actually pay for certain drugs. In fact, the Committee has identified prices that are routinely made available to many providers, but are far below Medicare reimbursement rates. These include 1999 prices for Vancomycin, the Abbott Labs-manufactured antibiotic, which a health care provider could buy for $76.00, but for which the AWP upon which Medicare's reimbursement was based was $261.84. Similarly, in 1998 a health care provider could buy Gensia's Etoposide for $14.00, while the AWP used to determine Medicare reimbursement was $141.97. Also in 1998, Pharmacia-Upjohn's Bleomycin had an AWP of $309.98, but health care providers could purchase it for $154.85. In 1997, Pharmacia-Upjohn's Vincasar could be purchased for $7.50, while the AWP was a staggering $741.50. (Attachment 1)

Note: The attachment above and the attachments that follow require the free Adobe Acrobat Reader to view. (www.adobe.com)

It must be stressed that 20% of these inflated Medicare payments come directly out of beneficiaries' pockets. In fact, in numerous instances, the 20 percent co-payment paid for a drug by a Medicare beneficiary alone exceeded the actual cost of the drug to the health care provider, not even

including the 80 percent payment made by Medicare. For the chemotherapy drug Leucovorin, a Medicare beneficiary paid $4.36 in 1996, for a drug that his or her health care provider could have purchased for only $1.89. That same provider received a total combined payment from Medicare and the patient of $21.53. (Attachment 2)

In addition, larger provider group practices or businesses employing numerous health care providers often obtain further additional steep discounts, which are often provided in the form of rebates or free goods. Wholesalers also obtain additional discounts through the use of chargebacks, which reflect reduced prices made available to their customers. (Attachment 3)

The Committee also has uncovered evidence that, in some instances, certain manufacturers have returned cash to health care providers purchasing their drugs, describing these questionable payments as educational grants, marketing grants, payments for data gathering or administrative fees, all of which appear to have been provided for the purpose of further lowering the actual cost for particular drugs and increasing the Medicare spreads. (Attachment 4) Many of these schemes are deliberately structured so as to not appear on any invoice or other billing record. As a consequence, any efforts to use actual acquisition costs for drugs to determine reimbursement amounts, including the proposals made in the President's last two budgets, would fail to detect many of these deep discounts.

In addition, the Committee's investigation uncovered a document containing a manufacturer's claim that certain health care providers were using its competitor's drug to fraudulently increase their profits by using less than an entire dose of a drug, but billing Medicare as if a full dose were administered, and then submitting additional bills for the use of the remainder of the dose. (Attachment 5)

Setting and Marketing of the Spread

Several drug manufacturers, in their initial replies to Committee requests for information, stated that they did not establish the amount of reimbursement provided by Medicare for their drugs. However, documents obtained by the Committee clearly indicate that not only do manufacturers routinely report numbers upon which the AWP is set, but also some of these manufacturers are inflating the prices they report in order to artificially increase the Medicare reimbursements, and the corresponding profits available to providers based upon the use of particular drugs. (Attachment 6)

The Committee has discovered evidence that strongly suggests that several drug manufacturers are deliberately promoting the sales of their drugs based on the excess payments for their drugs under Medicare, which constitute a direct monetary windfall for a provider. These excess payments are referred to by a variety of terms, including "spread," "return-to-practice," "return-on-investment," or most explicitly "profit." Manufacturers often prepare side-by-side comparisons of the spreads available on their drugs versus their competitors, which are then sometimes used to promote sales to providers. (Attachment 7)

These comparative analyses are often quite detailed, including estimates of potential profits available to a health care provider over the course of

treating a large number of Medicare patients. In one particularly egregious example, GlaxoWellcome marketed its anti-nausea drug Zofran by promoting the fact that a health care provider could make $84.59 in profit every time he or she administered that drug. Glaxo further estimated that the profit available for Zofran was $12.32 more than the profit available from a competitor product manufactured by SmithKline Beecham, and that a medical practice that administered 165,000 doses of Zofran could earn over two million dollars of additional profit for that practice by choosing Glaxo's product. (Attachment 8)

In addition, the Committee's investigation revealed that manufacturers have carefully analyzed how their competitors' sales representatives were deliberately promoting the profits available from Medicare as a powerful selling tool. In some instances, these companies actually prepared written complaints about such efforts, although they ultimately decided not to forward this information to government authorities, possibly due to fears of exposing their own practices. (Attachment 9)

Impact of the Spread on Utilization Decisions

The Committee's investigation also uncovered evidence indicating that manufacturers believe that the sales and utilization of their drugs could be hampered by smaller spreads, regardless of therapeutic benefit to patients. Documents from various manufacturers explicitly discuss how the profit available to health care providers appeared to be the primary reason why these health care providers were willing to administer the therapeutically equivalent but more expensive drugs of their competitors. (Attachment 10)

One manufacturer in particular was concerned that it would be very difficult to increase the sales of a therapeutically-superior second-generation product, because the spread on its earlier product was so great that health care providers would decline to use the newer drug, even though it had significant clinical advantages in treating patients. (Attachment 11)

The Committee's investigation also uncovered disturbing evidence that many health care providers may be making clinical decisions based more on the profit available from the use of a particular drug than any concern about a therapeutic outcome. The Committee reviewed utilization patterns of biological products in the State of Florida that strongly suggest that an exclusive focus on profit led health care providers to dramatically increase their use of a particular product -- which previously had been rarely utilized -- after the State Medicaid program significantly decreased the reimbursements available for all competitor products. (Attachment 12)

The Committee's investigation identified patterns of drug utilization based upon reimbursement that also may have frightening implications for public health. A review of utilization patterns strongly suggests that the use of vancomycin, the antibiotic of last resort used in treating otherwise deadly bacterial infections, may have dramatically increased as the result of the excessive Medicare spreads effectively created by Abbott Laboratories. (Attachment 13) Many experts believe that, as a result of such types of over-utilization, new vancomycin-resistant bacteria recently have emerged as a growing public health risk.

In addition to the above-referenced documents, the Committee has

identified several other documents that relate to these same issues, which I have included for your review. (Attachment 14)

Each of the examples cited above reveals how price manipulations by certain drug manufacturers -- as well as HCFA's failure to adequately define the statutory term "average wholesale price" to prevent such manipulations -- have caused Medicare to pay amounts far in excess of any reasonable estimation of a true average wholesale price. Proposals to reform the current system that continue to attempt to determine reimbursement based upon a percentage of AWP or actual acquisition cost are therefore doomed to fail, unless the types of abuses identified above are effectively addressed by HCFA through more vigorous oversight and improved regulations that ensure that prices being paid by Medicare reflect actual market-based prices, consistent with the intent of Federal law.

It is my hope that, by sharing this information with you, HCFA will finally begin to give this issue the priority it deserves, and will work harder to eliminate these abuses and better protect Medicare and its beneficiaries. I request that you provide the Committee with a monthly report detailing HCFA's progress in addressing this problem. If you should have any questions regarding any of the information provided above or on any related matter, please contact me or have your staff contact Charles Clapton, Committee counsel, at (202) 226-2424.

Sincerely,

Tom Bliley
Chairman

TB:cc

cc: The Honorable John D. Dingell, Ranking Member

Attachment 14

14-1 1131 kb
14-2 820 kb
14-3 254 kb
14-4 490 kb
14-5 217 kb
14-6 303 kb
14-7 99 kb
14-8 694 kb
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The Committee on Commerce
2125 Rayburn House Office Building
Washington, DC 20515
(202) 225-2927
Feedback

March 1997

Cancer Economics

Administration Proposes Cut Of Markup On Outpatient Drugs

The Administration's budget proposal for fiscal 1998 eliminates the markup on drugs and biologicals administered in physicians' offices and reimbursed under the Medicare program.

If adopted, the proposal would eliminate a major source of revenue for oncologists and, according to many observers, may lead physicians to administer chemotherapy in the hospitals, thereby actually increasing healthcare costs.

Under the existing law, Medicare reimburses 80 percent of the average wholesale price of a drug, and the patient pays the remaining 20 percent. Under the Administration's proposal, Medicare would reimburse 80 percent of the physicians' "actual acquisition cost."

In materials circulated on Capitol Hill, the American Society of Clinical Oncology said the proposal is "unworkable and unfair," and "may make it impossible for physicians to carry on their practices."

Under the Administration proposal, reimbursement would be the lowest of:

- The physician's actual acquisition cost.
- The average wholesale price.
- The median actual acquisition cost of all claims for the drug or biological for the 12-month period.

The proposal defines the actual acquisition cost as "the physician's... cost based on the most economical case size in inventory on the date of dispensing or, if less, the most economical case size purchased within six months of the date of dispensing whether that specific drug was furnished to an individual whether or not enrolled under this part. The actual acquisition cost includes all discounts, rebates, or any other benefit in cash or in kind (including, but not limited to, travel, equipment, or free products)."

Under the proposal, pharmacies could be paid "reasonable" dispensing fees.

In a critique of the proposal, ASCO said:

—The Proposal Is Not Based on True Acquisition Cost. Although ostensibly basing Medicare payment o

(Continued to page 2)

Insurers Are Eliminating Markup On Cancer Drugs, Official Says

Health insurers are starting to eliminate the oncologists' markup on chemotherapy drugs, a senior managed care company official said at a meeting of the National Cancer Centers Network earlier this month.

"You are going to have to make chemotherapy a cost-neutral equation," Lee Newcomer, chief medical officer at United HealthCare Corp. of Minneapolis, said in a keynote address at the NCCN guideline conference March 3. "I will tell you that the industry is probably going to do this for you.

"Without [eliminating the markup on drugs], I really do fear that you are going to lose credibility within organizations outside," said Newcomer, formerly a practicing oncologist. "Employers are already bringing this up to me. What are you doing about oncologists who are making too much money on drugs?"

The excerpted text of Newcomer's remarks follows:

"You need to go out and measure your performance, and you need to do it tomorrow. The only thing that makes you different from anybody else down the street is what you can come back and show me that you do.

"When you [measure performance], a couple of things are going to happen. First, you are not going to

(Continued to page 2)

ASCO Criticizes Administration Proposal On Drug Markup

(Continued from page 1)

on a physician's acquisition cost, the proposal would actually establish arbitrary rules that are only remotely connected to the acquisition cost of the drug being reimbursed. Actual acquisition cost would be capped by a national median based on prices 6-18 months old regardless of current market conditions. These rules would result in out-of-pocket losses by physicians.

—The Proposal Ignores Costs Incurred by Physicians. Even if acquisition cost were accurately computed, reimbursement on that basis would not cover all the costs. Additional costs include staff time in procuring and storing the drug; the opportunity cost of the capital tied up in drug inventory; wastage and spillage; sales tax in several states; and unpaid coinsurance

—The Proposal Would Create an Accounting Nightmare for Physicians. Drug companies may offer pricing that covers more than one product; there may be year-end rebates based on the amount of drug purchased; the purchase of one product may earn a discount on another product; free vials may accompany a number of purchased vials, etc. Physician practices are in no position to sort through these complexities and determine the cost of each drug, but if they make any errors in calculating the cost of a particular drug, they may be charged with making false claims.

Cancer Economics
A Monthly Supplement to The Cancer Letter

Editor: **Paul B. Goldberg**
Associate Editor: **Kirsten Goldberg**

P.O. Box 9905, Washington, D.C. 20016
Tel. (202) 362-1809 Fax: (202) 362-1681
Editorial e-mail: paul@www.cancerletter.com

Published 12 times a year by The Cancer Letter Inc. as a supplement to The Cancer Letter. Also publisher of The Clinical Cancer Letter.

—The Proposal Would Lead to Overall Inadequate Reimbursement. The current payment system for drugs compensates for Medicare's gross underpayment for the administration service. Currently, the Medicare payment for the basic infusion service is only about $53 even though the direct costs (staff, supplies) of the service have been determined by Medicare to be $102 and total costs (including rent, utilities, etc.) may be about $185. Until Medicare rectifies the payment amount for the administration service, physicians rely on the drug payments to cover their costs. If their costs are not covered, physicians cannot carry on their practices.

—The Proposal Would Be Anti-Competitive. Under the proposal, physicians would have no incentive to seek lower drug prices and manufacturers would have no incentive to compete on the basis of price. Drug prices could rise as a result. Because of the adverse incentives of cost reimbursement, Medicare is moving away from other services.

Health Insurance Official Says Industry Is Ending Markup

(Continued from page 1)

like what you find. You are human. You are just like any other doctor out there. Your performance will not be good.

"But then you know where to start. And you know what to improve. And you know what to do next...

"At United HealthCare, we have a concept that I call accountable autonomy.

"I don't want to be in the business of micromanaging. What I want to do instead is say, here are the standards. This is what you need to get to. You get there the way that works best for you. It may be the NCCN guidelines. It may be something entirely different. It may be that you need to work with your hospital to become more efficient.

"What we want to do is set the standards and set the rewards for meeting those standards and get out of the way.

"I think these guidelines are too complex for the average practicing doctor. Maybe what they need to do is measure how well they do on five or three key points of those guidelines as a starting points. There are too many branches and trees out there that it would take a very sophisticated computer system to get it all

done. You might be able to do that at NCCN locations, but you probably aren't going to get it out of the average oncologist's office.

"Today there is no extra incentive or financial payment for collecting data, but it is your key to staying in business five—well, actually two-to-five—years from now. Because the people who can come in and say, I can perform at an X level, and I have the data to prove it are the people who are going to be differentiated.

"Already, this year, we've gone to all the centers in our network who do high dose chemotherapy with some type of hematologic rescue, and we've set performance standards. For each diagnosis and stage, we said you have to hit this survival, and if you don't we are going to find someone else who can. What we are interested in is performance; not production.

"The second thing I'd ask you to do is become the personal care physician for the cancer patient. My fear for medical oncologists is that they are becoming nothing more than chemotherapy technicians. When you look at what's happened to oncology practices over the last five years, they've gone from being the cancer consultants to being chemotherapy givers.

"My case managers are coming to me and saying that about half my patients are dying within two weeks of their last chemotherapy course. So where was the oncologist saying, it's time for palliative care. Let me give you good supportive care and pain relief. Let me get you into a hospice. Let me help you with those things that are now important at this stage of your illness. Instead what is happening is they continue to get treated, and treated, and treated.

"And more and more we are finding that the type of treatment you get is directly related to which doctor you see first. If you are dealing with a cancer that has three options, surgery, radiation and oncology, what happens is you get surgery if you see a surgeon, radiation therapy if you see a radiologist, and chemotherapy if you see an oncologist.

"I think the oncologist should be the gateway for these folks into all the rest of the healthcare system. But to do that, you have to remain the general consultant for oncology.

"The markups for chemotherapy medicines are getting to be so high that the public is beginning to react. You are losing credibility from that. What you will see happening in my company and, I suspect, others, is that you will no longer be getting reimbursed at [Average Wholesale Price]. You will be getting reimbursed at catalogue prices. The reason for doing that is to make this decision truly a decision made because it's the right thing to do; not because you have a financial incentive.

"You shouldn't be making the decisions with the incentive that may not be the right incentive for you.

"We are on a brand new horizon in medical care. We have not known it, but we have been going along with mediocre performance for a long time. The next decade is going to bring superb performance."

In other developments at NCCN:

—The Network which includes 15 academic cancer centers, presented its clinical guidelines for sarcoma, melanoma, and cancers of the brain, head and neck, bladder and the pancreas, as well as a guideline on the use of antiemetics.

—Robert Young replaced Joseph Simone as NCCN chairman of the board. Young, formerly NCCN vice chairman, is president of Fox Chase Cancer Center. Simone is executive director of Huntsman Cancer Care Program.

Oncology Management

AOR, Immunex In Partnership On Studies Of Firm's Products

American Oncology Resources Inc., (Nasdaq: AORI) of Houston, and **Immunex Corp.** (Nasdaq: IMNX) of Seattle have formed a Disease Management Partner Program, the companies said.

According to the companies, the program is designed to improve cost effectiveness of cancer treatment delivered by the AOR network.

Under the agreement, AOR physicians will be involved in clinical studies of Immunex products, including a multi-state study of Novantron in advanced prostate cancer patients, the companies said. Immunex will supply 5 cancer-related therapeutics including Leukine (sargramostim) and Novantrone (mitoxantrone for injection concentrate) as well as generic products.

* * *

Joseph Welfeld was named president and CEO of **Affiliated Physicians Network Inc.** of White Plains, NY, a regional network of 120 physicians specializing in oncology.

Welfeld, most recently a consultant, is the former CEO of Ocean State Physicians Health Plan Inc., and regional vice president of United HealthCare Corp.

APN serves the New York metropolitan area

ASCO Tells Medicare What Is Acceptable

ALEXANDRIA, Va.—The American Society of Clinical Oncology has laid its cards on the table in the impending struggle over Medicare reimbursement for cancer drugs and their administration in the office.

In a "white paper" posted on its Web site this month, ASCO concluded that practice expenses covered by Medicare need to be revised to cover the true costs incurred by physicians in providing chemotherapy services. ASCO also asked that Medicare cover cognitive services as well.

At the same time, ASCO agreed that Medicare payment for drugs could be based on government surveys of wholesaler selling prices, or on the existing average wholesale price system "as modified to limit the permissible difference between actual selling price and published average wholesale price."

In a line in the sand on drug-cost reimbursement, ASCO proposed that three criteria were essential. Payments should be set at amounts that will cover the costs incurred by the vast majority of oncologists and should not require oncologists to alter their typical current procurement method of buying drugs from one or two wholesalers.

Any payment system based on an estimate of market prices should include a 10% add-on to cover additional drug-related costs, such as inventory expenses, bad debt, and wastage. Medicare should also pay state and local sales taxes and gross receipts taxes.

ASCO rejected the concept of a system of reimbursing each physician for the specific costs incurred by the physician for drugs administered to Medicare patients, contending that this has serious defects.

Meanhile, Brian McCagh, executive director of the Washington Cancer Institute, part of 791-bed Washington (D.C.) Hospital Center, was quoted this week in *Modern Healthcare* as summing up the issue bluntly.

"For many of the private-practice oncologists, it's not uncommon where up to 50% of their annual take-home pay can be tied directly back to the markup on the drugs they prescribe in their cancer practice," the magazine quoted McCagh, a former president of the Association of Cancer Executives, as saying. "How much longer will HCFA allow us to buy something for X (dollars) and try to sell it for three or four (times) X? Eventually, HCFA and managed-care organizations will crack down on this, and the question is just how much will they chip away at those margins."

Imatinib Resistance

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In accelerated-phase CML, the phase-2 data showed a 69% hematologic response lasting four or more weeks—an increase from the 63% hematologic response reported in February. About 70% of patients remain free of progression to the blast crisis after a year of treatment, the company reported.

In blast crisis, the updated data indicate that 52% of patients had some hematologic response, with 29% showing a sustained response for at least four weeks—up from the 26% reported in February.

And 65% of the patients who had achieved a hematologic response in the blast crisis phase have maintained it for six months or more, an estimated median duration of response of 8.3 months. For the entire blast crisis cohort, irrespective of response, the median survival rate is seven months, vs. three to six months for historical controls.

In the Pipeline

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SLN Agent in Trial

Memorial Sloan-Kettering Cancer Center researchers have completed the enrollment of patients with breast cancer in a phase-3 trial of Lymphazurin (patent blue V) injection, a radioactive iodine-labeled colloid of human albumin, as a sentinel lymph node agent.

ABX-EGF in Combo for NHL

Abgenix Inc. of Fremont, Calif., has received orphan drug designation from the FDA for its experimental ABX-EGF for NHL in combination with cisplatin and [illegible] a phase 1 trial of ABX-EGF as a single agent for refractory NHL will be initiated [illegible] this month.

Celgro's Phase-1/2

Celgro Pharmaceuticals of Austin, Texas, has initiated preliminary results of a phase-1/2 trial of Celgro, a synthetic anti-retinoic agent, for primary and unresponsive tumors of the pancreas, liver, prostate, and kidney, refractory or recurrent ovarian, cervical, and thyroid cancers, and melanoma and sarcoma of bone or soft tissue in pediatric patients. The agent is a retinoidal compound, inducing [illegible] on the normal cells of tissues and organs [illegible] to kill the tumors.

TLK286 for NSCLC

Trigen of Seattle has received orphan drug designation from the FDA for its TLK286 for the treatment of non-small cell lung cancer. The agent is a glutathione analog that is [illegible] glutathione S-transferase P1-1, which is overexpressed in many tumor cells. Trigen is also developing TLK286 for ovarian cancer.

Alkylating Agent in Phase-1

Van Andel Research Institute of Grand Rapids, Mich., has initiated a phase-1 trial of its alkylating agent VAN-1 in patients with advanced solid tumors. The agent is designed to [illegible] cross the blood-brain barrier.